BMJ Open

Early diagnosis of mortality using admission CT perfusion in severe traumatic brain injury patients (ACT-TBI): protocol for a prospective cohort study

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To cite: Alcock S, Batoo D, Ande SR, *et al*. Early diagnosis of mortality using admission CT perfusion in severe traumatic brain injury patients (ACT-TBI): protocol for a prospective cohort study. *BMJ Open* 2021;**11**:e047305. doi:10.1136/bmjopen-2020-047305

► Prepublication history and additional online supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-047305).

Received 24 November 2020
Accepted 17 May 2021

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ABSTRACT

Introduction Severe traumatic brain injury (TBI) is a catastrophic neurological condition with significant economic burden. Early in-hospital mortality (<48 hours) with severe TBI is estimated at 50%. Several clinical examinations exist to determine brain death; however, most are difficult to elicit in the acute setting in patients with severe TBI. Having a definitive assessment tool would help predict early in-hospital mortality in this population. CT perfusion (CTP) has shown promise diagnosing early in-hospital mortality in patients with severe TBI and other populations. The purpose of this study is to validate admission CTP features of brain death relative to the clinical examination outcome for characterizing early in-hospital mortality in patients with severe TBI.

Methods and analysis The Early Diagnosis of Mortality using Admission CT Perfusion in Severe Traumatic Brain Injury Patients study, is a prospective cohort study in patients with severe TBI funded by a grant from the Canadian Institute of Health Research. Adults aged 18 or older, with evidence of a severe TBI (Glasgow Coma Scale score ≤8 before initial resuscitation) and, on mechanical ventilation at the time of imaging are eligible. Patients will undergo CTP at the time of first imaging on their hospital admission. Admission CTP compares with the reference standard of an accepted bedside clinical assessment for brainstem function. Deferred consent will be used. The primary outcome is a binary outcome of mortality (dead) or survival (not dead) in the first 48 hours of admission. The planned sample size for achieving a sensitivity of 75% and a specificity of 95% with a CI of ±5% is 200 patients.

Ethics and dissemination This study has been approved by the University of Manitoba Health Research Ethics Board. The findings from our study will be disseminated through peer-reviewed journals and presentations at local rounds, national and international conferences. The public will be informed through forums at the end of the study.

Trial registration number NCT04318665

Strengths and limitations of this study

- This prospective cohort study hopes to improve clinical practice by establishing CT perfusion (CTP) as a diagnostic triage tool which could assist in diagnosing brain death in patients with severe traumatic brain injury (TBI) on admission.
- Our study is the first if its kind where CTP is done at the time of the standard imaging on arrival to hospital.
- This study includes a diversified population of severe TBI patients who are treated at our Provincial Trauma Centre (Health Sciences Centre, Winnipeg).
- Patients receive institutional standard of care after CTP.
- CTP is compared with a reference standard clinical assessment for brainstem function.

INTRODUCTION

Globally, over 50 million people are estimated to suffer a traumatic brain injury (TBI) annually.[1] The global economic burden of TBI is estimated at approximately US$400 billion per annum.[1] Primarily affecting healthy individuals with an excellent quality of life, TBI can result in a catastrophic injury, which makes it a huge public health challenge.[2] In Canada, it is anticipated that TBI will be the most prevalent and costly neurological condition through the year 2031, as it will account for a total indirect cost of over US$8 billion.[3] Furthermore, TBI represents a substantial expenditure for Canadian insurance companies dealing with medical insurance for rehabilitation therapy.[3]

Severity of TBI is classified into mild, moderate, and severe categories using the Glasgow Coma Scale (GCS), with 'severe TBI' defined as a GCS score ≤8.[3] Known as

the deadly killer or silent epidemic, severe TBI is believed to be the primary cause of postinjury hospitalisation, disability and death throughout the world.[3 4] Severe TBI is a life-threatening clinical emergency, during which trauma teams work swiftly in tandem to provide high-level trauma care. Despite very resource-intense care, which may include multiple complicated surgeries, the mortality rate for severe TBI patients within the first 48 hours post-admission remains at 50%.[2 5] Early in-hospital mortality (<48 hours) is likely dependent on the 'preinjury' and more likely on the 'injury' factors.[1 6] It is plausible that a significant percentage of these patients have permanent brain damage at the time of hospital admission, including brain death.

Clinical examination for confirmation of brain death

The clinical examination is the gold standard for diagnosing brain death.[7] In patients with severe TBI, it can be complicated to elicit because of the nature of the injury itself, and the fact that most patients are on life support and or sedative medications. Therefore, patients often receive elaborate resource-intense treatment despite a lack of clear prognoses. Adding to the quandary of the clinical exam is the fact that there are several outcome scales proposed for the final neurological outcome.[1] The sheer existence of numerous outcome scales reflects the complexity of long-term outcome assessments in patients with severe TBI. The most used outcome scale is an eight-point extended Glasgow Outcome Scale (GOSe).[8]

A poor neurological outcome is characterized by a GOSe score of 1 (death), 2 (vegetative state), 3 (severe disability) or 4 (moderate disability).[8] This outcome assessment is further complicated by preinjury and injury factors as well as patients' response at various stages. The absence of a definitive, reliable, validated, and timely triage tool to predict the higher in-hospital mortality of patients with severe TBI, warrants the urgent need of research in this field. This research may help reduce resource intensive and sometimes futile care in those who are already dead at the time of hospital admission. This may also facilitate the precious gift of organ donation.

Imaging for confirmation of brain death

Recent systematic reviews and recommendations have found that standard diagnostic imaging techniques (plain CT (CT) and CT angiography (CTA)) currently used to diagnose brain death have inadequate sensitivity.[9–11] This strengthens the need for advanced techniques to facilitate the early diagnosis of brain death.

Standard of care imaging performed on admission and during the hospital stay of a severe TBI patient is the plain head CT.[12] Plain CT accurately and promptly diagnoses structural abnormalities but does not provide any functional information including information on brain death.[12–17]

CTA is a readily available, practical, and omnipresent imaging test. However, the CTA protocol for confirmation of brain death varies considerably among different centres, which makes it difficult for it to be accepted as the gold-standard test.[18] Systematic reviews of the literature have concluded that the sensitivity of CTA is inadequate to confirm brain death and that clinicians should be wary when using it as an ancillary test.[9 10] Moreover, CTA provides anatomic, but not functional, information about the brain.[19]

CT perfusion (CTP) is an advanced CT scan that provides both functional and anatomic information about the brain, and it is mainly used to triage patients with acute stroke.[20–25] In this technique, the temporal change in contrast density is used to quantify perfusion parameters such as cerebral blood flow (CBF) and cerebral blood volume (CBV), which indicate areas of ischaemic or infarcted brain (areas of 'dead brain'). CTP is very sensitive in detecting CBF and can detect decreased perfusion as low as 2%–3% in CBF and 2% in CBV.[26] CBF <5 mL/100 g/min is consistent with clinical diagnosis of brain death.[27 28] If CTP is unable to detect CBF, or if CTP shows markedly decreased CBF (<5 mL/100 g/min), brain death can be confirmed because cellular viability is not possible at such a low CBF. Moreover, CTP with approximately whole-brain coverage can also provide data for CTA.

CTP has rarely been used for patients with severe TBI due to lack of reliable evidence on the efficacy of CTP in this patient population. One of the first uses of CTP in patients with severe TBI on hospital admission, was described by Wintermark *et al*.[29] [29] They found a favourable outcome, which was assessed at 90 days postadmission in patients with normal or high brain perfusion on admission CTP and an unfavourable outcome in patients with low perfusion. Bendinelli *et al*[30] performed CTP in patients with severe TBI who did not improve neurologically during the first 48 hours after trauma. They found low perfusion in one third of their patients. Additionally, they discovered that CTP altered clinical management in 10% of their patients who were diagnosed with massive and fatal strokes despite minimal changes on plain CT of head. Of importance, both studies used CTP with limited brain coverage due to technological limitations at the time; this may have missed key findings in other parts of the brain. These two studies addressed the neurological outcome at the end of the hospital stay, but failed to specify any association of CTP results with in-hospital mortality. We were the first to describe the CTP features of brain death as the most sensitive and specific imaging test for confirmation of brain death in intensive care unit (ICU) patients.[2 5] Furthermore, we provided the evidence of using CTP to predict in-hospital mortality in comatosed cardiac arrest patients.[31]

A triage tool to facilitate early, if not immediate, decision making is imperative as most deaths occur within 48 hours of hospital admission.[19 31] The first 48 hours of hospitalization involves the most resource-intensive medical and surgical care activities. Some patients with severe TBI may be dead by neurological definition at the time of their hospital admission. Since, an accurate clinical diagnosis

is obscured by anaesthetic and neuromuscular blockade agents, a validated admission CTP triage tool could assist in diagnosing brain death in these patients. In a small pilot study, our group has shown that CTP could show mortality in 25% of patients at the time of their hospital admission.[32] We hypothesize that in severe TBI patients, the CTP scan done at the time of hospital admission, can diagnosis brain death reliably as opposed to the current clinical examination which is routine practice.

The primary objective of the Early Diagnosis of Mortality using Admission CT Perfusion in Severe Traumatic Brain Injury Patients (ACT-TBI) study is to validate admission CTP features of brain death, relative to the clinical outcome of death versus survival, in the first 48 hours of hospital admission, among patients with severe TBI. Secondary objectives include: (1) to establish the safety of admission CTP; (2) to establish the inter-rater reliability of features of brain death on admission CTP.

METHODS AND ANALYSIS

The ACT-TBI study, is a prospective cohort study in patients with severe TBI, which builds on previous work by our team.[32] The study design was conceptualized by experts in content (trauma/critical care neurosurgery, neuroradiology, emergency medicine and critical care), epidemiology, and clinical trials to ensure a high-quality study. The ACT-TBI study is under way at the Health Sciences Centre, which is the provincial trauma centre.

Study population

Our study population of interest are patients with severe TBI who meet the following inclusion criteria: (1) at least 18 years old; (2) severe head injury; (3) GCS score ≤8 after initial resuscitation and (4) on mechanical respiratory ventilation at the time of imaging. Study exclusion criteria include: (1) no known GCS after initial resuscitation; (2) known pregnancy; (3) known contraindication to CT contrast agent, for example, allergy or anaphylactic reaction and (4) known end-stage renal disease.

Patient and public involvement

Survivors of TBI and their families were involved in the planning, design, recruitment and conduct of the study.

Study Intervention-

All eligible consecutive patients will be screened and enrolled by the treating emergency department (ED) physician during the initial hospital admission resuscitation, and then undergo a standard imaging protocol, (whole body CT scan, including the plain head CT) as well as the study CT-perfusion protocol of the whole head (figure 1). Images will be acquired following our previously published protocol.[32] In brief, a total of 40 mL of CT contrast media will be injected at a rate of 5 mL/s. A set of axial images with a slice thickness of 5 mm for the perfusion analysis will be reconstructed. All patients will receive standard of care post imaging and the results of the CTP will not be made available to the clinical team involved in patient care, since the prognostic value of CTP has not been established in this patient population.

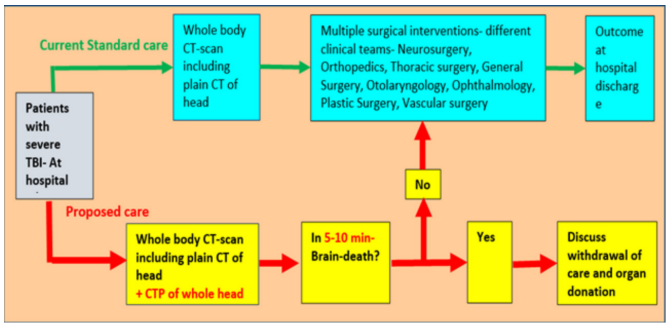

Figure 1 Illustration of the current hospital standard of care workflow (in blue) for severe TBI patients at admission and the intervention from our research protocol (in yellow). CTP, CT perfusion; TBI, traumatic brain injury.

Retention strategies

At our centre, one universal requisition is used for all diagnostic imaging tests. To improve study adherence and to remind the ED team of the study, a red stamp was placed on each requisition in the department (see figure 2). Furthermore, at the end of each month, the ED team and the Diagnostic Imaging team receive an email indicating the study's enrolment status, and a brief reminder of the study and its objectives. To facilitate the study's recruitment goal, the study team monitors the provincial diagnostic database system daily for CTP scans. A log of the screened patients is then kept by the study coordinator. The study design and intervention do not require significant changes to current standard clinical practice, as the addition of CTP images is the only change in practice. No issues are foreseen in data collection.

Timeline

We plan to complete the ACT-TBI study within 2 years. Study preparation including clinical research documentation, institutional ethics committee approvals, training of research staff involved in the study, and pilot validation took approximately 6 months. Ethics approval was obtained on 24 February, 2020. Actual patient enrolment began on 23 July, 2020. Most trauma centres receive a minimum of five patients with severe TBI per week. With a conservative enrolment rate of approximately 15–17 patients per month, the enrolment should be accomplished within 1 year. Data preparation including the CTP image analysis will commence in the final year of the study. A description of the study timeline can be found in table 1.

Data Collection and Management

Clinical data

Clinical data will be collected by a qualified data abstractor with knowledge of the study. A qualified data abstractor will collect data from the patient's chart using a chart abstraction tool. The case report form for our study can

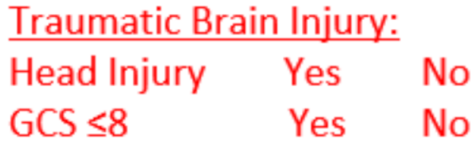

Figure 2 Study stamp for the diagnostic imaging requisition.

be found in online supplemental appendix A. Existing injuries will be documented using the new Injury Severity Scale.[33] Process metrics such as, the number of surgical interventions on each patient, the length of stay in ICU, and the hospital length of stay will be derived from the data collected. All clinical data will be entered into an Excel database. Clinical Data cleaning and validation will be completed by a master's student. The principal investigator will ensure quality assurance policies are being implemented to confirm study data are reported in compliance with the protocol, which include: reviewing the screening logs; monitoring of recruitment trends; reviewing the data collected on the case report forms; generating queries regarding outliers or missing data and implementing data tracking procedures.

Imaging data

CTP images will be acquired at the time of admission. An overview of the imaging data collected for our study can be found in online supplemental appendix A. The anonymized images will be transferred and stored in the secured imaging core lab in the department of Radiology at the University of Manitoba. The imaging centre (Department of Radiology, University of Manitoba, Winnipeg) is responsible for the postprocessing of the CTP raw data, image interpretation and image analysis. CTP will be processed using a semiautomatic deconvolution algorithm on a vendor neutral software package (Oleasphere). CTP will be assessed quantitatively such that brain death will be defined as CBF <5 mL/100 g/min and CBV <2 mL/100 g in the brainstem. CTP will also be assessed qualitatively with brain death being defined as a matched decrease of CBF and CBV in the brainstem. During the first 48 hours of hospital admission and at the end of the patients hospital stay, the perfusion maps for CBF and CBV will be assessed for the binary outcome of 'dead' or 'not-dead', according to our previously published methods.[4 31–34] The perfusion images will be reviewed by two-independent neuroradiologists, who will be blinded to the clinical status of the patient and also to each other's assessment. In case of disagreement, a consensus agreement will be employed for the final analysis.

Table 1 Description of Timeline for the ACT-TBI study

	Year 1	Year 2
Protocol and CRF finalisation		
REB submissions and approvals		
Start-up meeting and training		
Site activation		
Screening and enrolment		
Data collection		
Steering committee meetings		
Adjudication		
Data preparation and analyses		
Dissemination		

ACT-TBI, Early Diagnosis of Mortality using Admission CT Perfusion in Severe Traumatic Brain Injury Patients; CRF, clinical record form; REB, research ethics board.

Data analysis and power considerations

The gold standard for diagnosis of brain death is confirmation by clinical examination. Sensitivity is defined as the ability of CTP to correctly classify an individual as 'dead', while ability of CTP to correctly classify an individual as 'not-dead' is a specificity. Positive predictive value (PPV) is the percentage of patients showing features of brain death on CTP, who are clinically 'dead'. Negative predictive value (NPV) is the percentage of patients with no features of brain death on CTP, who were clinically 'not-dead'. An ideal triage test for confirmation of brain death should have no false positives, that is, calling someone 'dead' when they are not. Thus, an ideal triage test should have 100% specificity and PPV. In our pilot study, CTP showed 100% specificity and PPV as well as 75% sensitivity and 94% NPV for correctly classifying in-hospital mortality. Based on these preliminary results by employing the Buderer's formula,[35] we calculated a sample size for the ACT-TBI study. A total of 180 patients with severe TBI (with a conservative prevalence of in-hospital mortality of at least 40%) will be required to validate the features of brain death on admission CTP against in-hospital mortality. This will allow us to achieve a sensitivity of at least 75% and specificity of 95% with a CI ±5% around the point estimate. Since the study endpoint is at hospital discharge, we do not expect any loss to follow-up. With a plausible drop-out of 10% (including technical problems with CTP acquisition, protocol violation, consent withdrawal or possible contraindication for CTP), the sample size was increased by an absolute number of 20. Thus, a total of 200 patients with severe TBI will be targeted to enrol in the ACT-TBI study.

Baseline characteristics of patients will be described using frequency distribution statistics and measure of dispersion. The primary validity analysis will be performed using sensitivity, specificity, PPV and NPV for features of brain death on admission CTP compared with the in-hospital mortality along with 95% CI. Area under the receiver operating characteristics curve will be calculated to characterize the diagnostic ability of brain death features on CTP for in-hospital mortality. Interobserver agreement between two neuroradiologists will be assessed using the kappa statistic to assess the reliability of CTP. Logistic regression will be used to build predictive models for clinical outcome at discharge for admission CTP, IMPACT variables,[36] and other standard baseline variables such

as age, sex, baseline GCS score, nature of the baseline head injury. The predictive models will be used to calculate the area under the receiver operating characteristics curve to enable comparison of the models. Complications including renal failure or allergic reactions associated with CTP will be reported in percentage.

DISCUSSION

Outcomes of the ACT-TBI study will validate the admission CTP as a pioneer triage tool, thereby offering improved diagnosis and prognosis for brain death in patients with severe TBI, which can be further confirmed by the clinical examination gold standard. Adopting this triage tool in the routine practice to evaluate patients with severe TBI will help reduce the use of resource intensive and sometimes futile treatment to potentially dead patients in the emergency room. Furthermore, using CTP in this setting will improve trust and investment in organ transplantation in Canada and worldwide.

One study limitation is that our prospective study is a single centre study; this may affect its generalisability. Our prospective study, however, has rigour in that the study intervention is controlled and the outcome measures are preselected. ACT-TBI study is the first of its kind where admission CTP will be used to assess mortality in patients with severe TBI at the time of hospital admission. Besides this vital objective, we also planned two nested studies: (1) to examine the imaging biomarkers as predictors of functional outcome in patients with severe TBI and pathological correlation of the imaging biomarkers on autopsy, when possible and on receiving the separate consent and (2) health economic benefits of employing admission CTP.

ETHICS AND DISSEMINATION

We have received ethics approval from the University of Manitoba Health Research Ethics Board number-HS23683- (B2020:018) and the study is being conducted in compliance with Good Clinical Practices on Ethical Conduct for Research Involving Humans.

Deferral of consent has been approved by our institutional ethics board. Considering the altered level of the participant's consciousness, informed consent will be obtained from a substitute legal decision-maker by deferred consent within 1 week of enrolment. Informed consent will be obtained by the site research coordinator/research nurse.

All data collected for the study will remain strictly confidential. Anonymity of the study participants is addressed by using case numbers. A record of the patient's ID and case number is being kept in a separate secure password-protected file accessible only by the study coprincipal investigators and study coordinator. Data will be presented in an aggregate form only. Data collection forms will be stored for at least 10 years.

The dissemination plan includes the traditional dissemination vehicles (eg, presentations at local grand rounds, national and international conferences, publications of studies in open-access peer-reviewed journals). Once proven useful, admission CTP will be incorporated in the clinical guidelines for imaging in patients with severe TBI. This will bring the evidence-based clinical practice change at the national and international level. The knowledge translation plan will also employ other approaches that will aim to incorporate the findings into the design of future studies. A Café Scientifique session at the end of the study will be organized to inform the general public about the results of our study and how it will influence future clinical practice. In completing the study monitoring activities, we will be conducting a type of ongoing general quality improvement in the care of patients with severe TBI. This will function as a mechanism of integrative knowledge translation that will ultimately be transferable to implementation of this treatment in routine clinical practice.

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Acknowledgements We are grateful to all the patients that participated in the study and would like to thank the Health Sciences Centre Adult Emergency for their involvement in subject recruitment and the CT technologists for performing the CT perfusion scans. We would also like to thank Cecelia and Steven Lipischak for their letter of support for our grant application, which was through the lens of a family member and patient.

Contributors JJSS, FAZ, RG, ME, DM, AT, NS and SRA contributed to the conception and design of the study, provided input into the protocol, and gave critical feedback on the manuscript. JJSS, SA and DB obtain consents. SA and DB perform study coordinator duties and collect clinical data. DB collects the imaging data. ML provides ongoing study support within the ED. JJSS, FAZ, RG, ML, SA and DB attend quarterly ACT-TBI steering committee meetings. SA wrote the initial draft of the manuscript. All authors approved the final version of the manuscript.

Funding This work is supported by the Canadian Institute of Health Research, grant number 201909PJM-432061-BSB-CDAA-283730. JJSS receives salary research support award from Radiology consultants of Winnipeg. FAZ receives research support from the Manitoba Public Insurance (MPI) Neuroscience/TBI Research Endowment, the Health Sciences Centre Foundation Winnipeg, the United States National Institutes of Health (NIH) through the National Institute of Neurological Disorders and Stroke (NINDS)(Grant #: R03NS114335-01), the Canadian Institutes of Health Research (CIHR)(Grant #: 432061), the Canada Foundation for Innovation (CFI)(Project #: 38583), Research Manitoba (Grant #: 3906), the University of Manitoba VPRI Research Investment Fund (RIF), the University of Manitoba Centre on Aging and the University of Manitoba Rudy Falk Clinician-Scientist Professorship.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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Appendix A. The Study Case Report Form

ACT-TBI-CRF **Patient Assessment** Patient ID: __ __ - __ __ __

1. Patient Assessment

1. Eligibility Criteria	**Yes**	**No**
1.1 Adults ≥ 18 years old	☐	☐
1.2 Severe head injury (GCS score ≤ 8 after initial resuscitation) with the activation of the trauma code on mechanical respiratory ventilation at the time of imaging	☐	☐
2. Inclusion Criteria		
Same criteria as eligibility		
3. Exclusion Criteria		
4. No known GCS after initial resuscitation		
4.1 Patients with contraindications to CT-perfusion		
4.1.1 Pregnancy	☐	☐
4.1.2 Contrast allergy	☐	☐
4.1.3 Clinician refuses because of kidney injury	☐	☐
4.1.4 Hemodynamic instability that prevents safe transport to the CT-scan	☐	☐

Version Date: March 4, 2021

ACT-TBI-CRF **Consent** Patient ID: __ __ - __ __ __

2. Consent

1. Date/time consent was obtained (DD/MMM/YYYY) (hh:mm)	___ ___ / ___ ___ ___ / 20 ___ ___ ___ ___ : ___ ___ (24hr)
2. Who provided consent?	□ Substitute Decision Maker □ Father □ Mother □ Brother □ Sister □ Spouse or partner □ Daughter □ Son □ Other (specify): _____

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ACT-TBI-CRF **Brain CT-Perfusion** Patient ID: __ __ - __ __ __

3. Brain CT-Perfusion

1. CT Brain Perfusion Data	
1.1 Date/time patient left ED to perform CT: (DD/MMM/YYYY hh:mm)	__ __ / __ __ __ / 20 __ __ __ __ : __ __
1.2 Time CT performed: (hh:mm)	__ __ : __ __ (24hr)
1.3 Time patient returned to ED after performing CT: (hh:mm)	__ __ : __ __ (24hr)
1.4 Contrast media injected (non-ionic iodinated):	□ 40 mL □ Other, specify: _____ mL
1.5 Type of contrast:	□ Isovue 370 □ Omnipaque 300 □ Omnipaque 350 □ Ultravist (iopromide) 370 □ Visipaque 320 □ Other (specify): _____

1.6 CTP-related events experienced by patient (check all relevant events):

Events marked by an * must be reported to coordinating center within 24h:

Study coordinator: Sudharsana Rao Ande, Tel 204 789 3996

or

Study PI: Dr Jai Shankar, tel 431-373-4164

Event	Time of occurrence	Requiring Treatment
☐ Hypertension (more than 180 mmHg systolic for 2 minutes)	__ __ : __ __ (24h)	□ Yes □ No If Yes, please specify: _____ _____ __
☐ Hypotension (less than 60 mmHg mean arterial pressure for 2 minutes)	__ __ : __ __ (24h)	□ Yes □ No If Yes, please specify: _____ _____ __
☐ New desaturation less than 88% for more than 1 minute	__ __ : __ __ (24h)	□ Yes □ No If Yes, please specify: _____ _____ __
☐ **Accidental extubation***	__ __ : __ __ (24h)	□ Yes □ No If Yes, please specify: _____ _____ __

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ACT-TBI-CRF Brain CT-Perfusion

Patient ID: __ __ - __ __ __

☐ New catheter dysfunction (obstruction, removal)	__ __ : __ __ (24h)	□ Yes □ No If Yes, please specify: _____ _____ __
☐ **Code blue (or equivalent)***	__ __ : __ __ (24h)	□ Yes □ No If Yes, please specify: _____ _____ __
☐ Other (specify): _____	__ __ : __ __ (24h)	□ Yes □ No If Yes, please specify: _____ _____ __
1.7 Iodine injection related events:		
☐ Minor adverse events (self-limiting, non-progressive): New: limited urticaria, limited cutaneous edema, rhinorrhea, conjunctivitis	__ __ : __ __ (24h)	□ Yes □ No If Yes, please specify: _____ _____ __
☐ Moderate adverse events (often require management): New: diffuse urticaria, facial edema, bronchospasm, mild hypoxia	__ __ : __ __ (24h)	□ Yes □ No If Yes, please specify: _____ _____ __
☐ **Severe reactions (often require intervention): *** New: diffuse erythema/edema with hypotension, laryngeal edema with strider and/or hypoxia, wheezing/bronchospasm, significant hypoxia, anaphylactic shock (hypotension + tachycardia)	__ __ : __ __ (24h)	□ Yes □ No If Yes, please specify: _____ _____ __
☐ No CTP or iodine injection related events		

2.	
2.1	

Notes: _____
_____
_____

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ACT-TBI-CRF **Baseline** Patient ID: __ __ - __ __ __

4. Baseline

1. Date of birth (MMM/YYYY)	___ ___ ___ / ___ ___ ___ ___
2. Date of injury (and approximate time) (DD/MMM/YYYY) (hh:mm)	___ ___ / ___ ___ ___ / 20 ___ ___ ___ ___ : ___ ___ (24hr)
3. Sex at birth	□ Male □ Female
4. Race	□ Asian □ Black or African American □ Caucasian □ First Nations □ Unknown □ Other, specify _____
5. Mode of trauma	□ Traumatic Brain Injury (TBI) □ Open TBI with intracranial hemorrhage □ Close TBI with intracranial hemorrhage □ Open TBI without intracranial hemorrhage □ Close TBI without intracranial hemorrhage □ Motor Vehicle injury □ Physical assault □ Gun-Shot injury □ Stabbing □ Electrocution □ Asphyxiation (choking or suffocation) □ Other, specify: _____

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ACT-TBI-CRF **Baseline** Patient ID: __ __ - __ __ __

6. Injury Severity Score Head and Neck	□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 (1-Minor; 2-Moderate; 3-Serious; 4-Severe; 5-Critical; 6 -Unsurvivable)
7. Injury Severity Score Face	□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 (1-Minor; 2-Moderate; 3-Serious; 4-Severe; 5-Critical; 6 -Unsurvivable)
8. Injury Severity Score Chest	□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 (1-Minor; 2-Moderate; 3-Serious; 4-Severe; 5-Critical; 6 -Unsurvivable)
9. Injury Severity Score Abdomen	□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 (1-Minor; 2-Moderate; 3-Serious; 4-Severe; 5-Critical; 6 -Unsurvivable)
10. Injury Severity Score Extremity	□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 (1-Minor; 2-Moderate; 3-Serious; 4-Severe; 5-Critical; 6 -Unsurvivable)
11. Injury Severity Score External	□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 (1-Minor; 2-Moderate; 3-Serious; 4-Severe; 5-Critical; 6 -Unsurvivable)
12. Weight at ED admission	_____ Kg
13. Height	_____ cm

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ACT-TBI-CRF **Baseline** Patient ID: __ __ - __ __ __

14. Comorbidities	□ Hypertension treated with medication □ Hypertension not treated or not known to be treated with medication □ Diabetes □ Coronary artery disease □ Peripheral vascular disease □ Previous stroke □ Active smoking □ Smoking history (known past history) □ Chronic renal failure with dialysis □ Chronic renal failure without dialysis □ Liver disease □ Other, specify _____ □ None □ None specified/unknown

15. Admission information	
Previous hospital (if patient transferred from another hospital):	
15.1. First hospital ED admission date/time (DD/MMM/YYYY hh:mm)	__ __ / __ __ __ / 20 __ __ __ __ : __ __ (24hr) □ Not applicable
15.2. First hospital discharge date/time (DD/MMM/YYYY hh:mm)	__ __ / __ __ __ / 20 __ __ __ __ : __ __ (24hr) □ Not applicable
Current hospital :	
15.3. ED admission date/time (if patient not transferred from another hospital) (DD/MMM/YYYY hh:mm)	__ __ / __ __ __ / 20 __ __ __ __ : __ __ (24hr) □ Not applicable
15.4. ICU admission date/time (DD/MMM/YYYY hh:mm)	__ __ / __ __ __ / 20 __ __ __ __ : __ __ (24hr)

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ACT-TBI-CRF **Baseline** Patient ID: __ __ - __ __ __

16. Record documented GCS at each of the following stage:		
16.1. On scene	Eye	___ □ Not available
	Verbal	___ □ Not available
	Motor	___ □ Not available
	Total	___ □ Not available
16.2. ED GCS (From first hospital: previous or current hospital)	Eye	___ □ Not available
	Verbal	___ □ Not available
	Motor	___ □ Not available
	Total	___ □ Not available
16.3. ICU GCS (From previous hospital if patient transferred)	Eye	___ □ Not available □ Not applicable
	Verbal	___ □ Not available □ Not applicable
	Motor	___ □ Not available □ Not applicable
	Total	___ □ Not available □ Not applicable
16.4. ICU admission of current hospital (first available)	Eye	___ □ Not available
	Verbal	___ □ Not available
	Motor	___ □ Not available
	Total	___ □ Not available

17. If patient transferred from another hospital: Last laboratory data measures available from previous hospital (specify value and date of test for each parameter)			□ Not applicable
Biochemistry			
17.1. Blood glucose (mmol/L):	_____	__ __ / __ __ __ / 20 __ __	□ Not available
17.2. Hemoglobin (g/L):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ Not available
17.3. Na+ (mmol/L):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ Not available
17.4. K+ (mmol/L):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ Not available
17.5. Creatinine (µmol/L):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ Not available
17.6. BUN (mmol/L):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ Not available

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ACT-TBI-CRF **Baseline** Patient ID: __ __ - __ __ __

Blood Gases (Specify method)	□ Arterial □ Capillary □ Venous __ __ / __ __ __ / 20 __ __ Use same method and gas for the following questions.		□ Not available
17.7. pH:	_____		
17.8. HCO3 (mmol/L):	_____		
17.9. PCO2 (mmHg):	_____		
17.10. PaO2 (mmHg):	_____		
17.11. FiO2 (%):	_____		
Vital Signs			
17.12. Systolic BP (mmHg):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ Not available
17.13. Diastolic BP (mmHg):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ Not available
17.14. MAP (mmHg):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ Not available
17.15. Heart Rate (bpm):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ Not available
17.16. Body Temperature (◦C):	_____ □ Rectal □ Oral □ Axillary □ Not specified □ Other, specify _____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ Not available
17.17. Total Fluid Balance (mL)	□ + □ – _____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ Not available

18. First available laboratory data in ED (current hospital) Specify value and date of test for each parameter.			
Biochemistry			
18.1. Blood glucose (mmol/L):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ NA
18.2. Hemoglobin (g/L):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ NA
18.3. Na+ (mmol/L):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ NA
18.4. K+ (mmol/L):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ NA
18.5. Creatinine (µmol/L):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ NA
18.6. BUN (mmol/L):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ NA
Blood Gases (Specify method)	□ Arterial □ Capillary □ Venous __ __ / __ __ __ / 20 __ __ Use same method and gas for the following questions.		□ NA
18.7. pH:	_____		

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ACT-TBI-CRF **Baseline** Patient ID: __ __ - __ __ __

18.8. HCO3 (mmol/L):	_____		
18.9. PCO2 (mmHg):	_____		
18.10. PaO2 (mmHg):	_____		
18.11. FiO2 (%):	_____		
Vital Signs			
18.12. Systolic BP (mmHg):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ NA
18.13. Diastolic BP (mmHg):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ NA
18.14. MAP (mmHg):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ NA
18.15. Heart Rate (bpm):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ NA
18.16. Body Temperature (◦C):	_____	□ Same date as above OR __ __ / __ __ __ / 20 __ __	□ NA
	□ Rectal □ Oral □ Axillary □ Not specified □ Other, specify _____		

Surgery /Interventions

19. Date of Operations/Interventions (DD/MMM/YYYY) (hh:mm)	___ ___ / ___ ___ ___ / 20 ___ ___ ___ ___ : ___ ___ (24hr)
20. Operation/Intervention List date and time with each.	

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ACT-TBI-CRF **Daily Data Collection** Patient ID: __ __ - __ __ __

5. Daily Data Collection

Clinical data for 7 days after inclusion into the study						
□ Day 1 (Enrollment Date)	□ Day 2	□ Day 3	□ Day 4	□ Day 5	□ Day 6	□ Day 7

1. Date (DD/MMM/YYYY)		__ __ / __ __ __ / 20 __ __	
2. GCS*		**Worst value of the day** □ with sedation □ without sedation	**Best value of the day** □ with sedation □ without sedation
• Eye		___	___
• Verbal		1 (T)	1 (T)
• Motor		___	___
• Total GCS & time of assessment (hh:mm)		___ @ __ __ : __ __	___ @ __ __ : __ __
Complete the questions 2.1 to 2.6 if the total GCS best value is more than 3: □ Not applicable		**Cranial nerve territory response**	**Peripheral nerve territory response**
2.1. Painful stimulation above clavicles		□ Absent □ Present □ Not available	□ Absent □ Present □ Not available
2.2. If presence of a peripheral response, is that response a spinal reflex?		□ Yes, it is a spinal reflex □ Both spinal and upper motoneuron mediated reflexes present □ No, it is an upper motoneuron mediated reflex □ Unsure □ Not available	
2.3. Pupillary response to light	Right	□ Absent	□ Present □ Not available
	Left	□ Absent	□ Present □ Not available
2.4. Corneal response	Right	□ Absent	□ Present □ Not available
	Left	□ Absent	□ Present □ Not available
2.5. Cough reflex		□ Absent	□ Present □ Not available
2.6. Pharyngeal (gag) reflex		□ Absent	□ Present □ Not available

***Glasgow Coma Scale (GCS)**		
Eye GCS	**Verbal GCS**	**Motor GCS**
4 – Spontaneously eye opening 3 – Eye opening in response to verbal command 2 – Eye opening in response to pain 1 – No response	5 – Orientated 4 – Confused conversation 3 – Words (inappropriate) 2 – Sounds (incomprehensible) 1 – No response	6 – Obeys (moves according to) verbal commands 5 – Localizes pain 4 – Flexion-withdrawal 3 – Flexion-abnormal/ decorticate rigidity 2 – Extension/decerebrate rigidity 1 – No response

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ACT-TBI-CRF Daily Data Collection

Patient ID: __ __ - __ __ __

3. Biochemistry

□ Day 1 (Enrollment Date)	□ Day 2	□ Day 3	□ Day 4	□ Day 5	□ Day 6	□ Day 7

3.1. Blood glucose (mmol/L):	Lowest: _____	Highest: _____	□ NA
3.2. Hemoglobin (g/L):	Lowest: _____	Highest: _____	□ NA
3.3. Platelets (10^9/L):	Lowest: _____	Highest: _____	□ NA
3.4. Na+ (mmol/L):	Lowest: _____	Highest: _____	□ NA
3.5. K+ (mmol/L):	Lowest: _____	Highest: _____	□ NA
3.6. Creatinine (μmol/L):	Lowest: _____	Highest: _____	□ NA
3.7. BUN (mmol/L):	Lowest: _____	Highest: _____	□ NA
3.8. Albumin (g/L):	Lowest: _____		□ NA
3.9. Total bilirubin (μmol/L):	Highest: _____		□ NA
3.10. AST (U/L):	Highest: _____		□ NA
3.11. ALT (U/L):	Highest: _____		□ NA

3.12. Has the patient any of the following Acute Kidney Injury criteria: • Increase in serum creatinine by ≥ 26.5 mol/l within 48 hours; • Increase in serum creatinine to ≥ 1.5 times baseline, which is known or presumed to have occurred within the prior 7 days; • Urine volume < 0.5 ml/kg/h for 6 hours.	□ Yes □ No	
3.13. What is the patient KDIGO Acute Kidney Injury Stage?	□ No Acute Kidney Injury	
	□ Stage 1	• Serum creatinine 1.5-1.9 times baseline OR ≥ 26.5 μmol/l increase • Urine output of < 0.5 ml/kg/h for 6–12 hours
	□ Stage 2	• Serum creatinine 2.0-22.9 times baseline • Urine output of < 0.5 ml/kg/h for ≥ 12 hours
	□ Stage 3	• Serum creatinine 3.0-22.9 times baseline OR Increase in serum creatinine to ≥ 353.6 μmol/l OR Initiation of renal replacement therapy • Urine output of < 0.3 ml/kg/h for ≥ 24 hours OR Anuria for ≥ 12 hours

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ACT-TBI-CRF Daily Data Collection Patient ID: __ __ - __ __ __

4. Blood Gases						
□ Day 1 (Enrollment Date)	□ Day 2	□ Day 3	□ Day 4	□ Day 5	□ Day 6	□ Day 7

Blood Gas based on lowest pH (Specify method)	□ Arterial □ Capillary □ Venous Use same gas for following questions.	
4.1. pH:	_____	□ NA
4.2. HCO3 (mmol/L):	_____	□ NA
4.3. PCO2 (mmHg):	_____	□ NA
4.4. PaO2 (mmHg):	_____	□ NA
4.5. FiO2 (%):	_____	□ NA
Blood Gas based on highest pH (Specify method)	□ Arterial □ Capillary □ Venous Use same gas for following questions.	
4.6. pH:	_____	□ NA
4.7. HCO3 (mmol/L):	_____	□ NA
4.8. PCO2 (mmHg):	_____	□ NA
4.9. PaO2 (mmHg):	_____	□ NA
4.10. FiO2 (%):	_____	□ NA

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ACT-TBI-CRF Daily Data Collection Patient ID: __ __ - __ __ __

5. Vital Signs						
□ Day 1 (Enrollment Date)	□ Day 2	□ Day 3	□ Day 4	□ Day 5	□ Day 6	□ Day 7

5.1. Systolic BP (mmHg):	Lowest: _____	Highest: _____	□ NA
5.2. Diastolic BP (mmHg):	Lowest: _____	Highest: _____	□ NA
5.3. MAP (mmHg):	Lowest: _____	Highest: _____	□ NA
5.4. Heart Rate (bpm):	Lowest: _____	Highest: _____	□ NA
5.5. Body Temperature (◦C):	Lowest: _____ Highest: _____ □ NA □ Rectal □ Oral □ Axillary □ Not specified □ Other, specify _____		
5.6. 24h Fluid Balance (mL):	□ + □ –	_____	□ NA

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ACT-TBI-CRF **Daily Data Collection** Patient ID: __ __ - __ __ __

1. Record all sedatives, analgesics, anti-psychotics, barbiturates & vasopressors/inotropes received **from day of ED arrival / enrolment .**

Sedatives - Bolus				☐ No data to report	
Please choose letter from table below	**Date Administered**	**Time Administered** (hh:mm)	**Route**	**Dose**	**Unit**
☐ ________________	__ __/ __ __ __/ 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ ________________	__ __/ __ __ __/ 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ ________________	__ __/ __ __ __/ 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ ________________	__ __/ __ __ __/ 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ _______________*	__ __/ __ __ __/ 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg

Sedatives – Continuous Infusion				☐ No data to report
Please choose letter from table below	**Date & Time Started**	**Date & Time Ended**	**Rate**	**Unit**
☐ ________________	__ __/ __ __ __/ 20 __ __ __ __ : __ __	__ __/ __ __ __/ 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ ________________	__ __/ __ __ __/ 20 __ __ __ __ : __ __	__ __/ __ __ __/ 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ ________________	__ __/ __ __ __/ 20 __ __ __ __ : __ __	__ __/ __ __ __/ 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ ________________	__ __/ __ __ __/ 20 __ __ __ __ : __ __	__ __/ __ __ __/ 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ _______________*	__ __/ __ __ __/ 20 __ __ __ __ : __ __	__ __/ __ __ __/ 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___

Table: Options for Sedatives			
A: Propofol (Diprivan) **B**: Midazolam (Versed)	**C**: Lorazepam (Ativan) **D**: Diazepam (Valium)	**G**: Clonazepam (Rivotril) **H**: Ketamine (Ketalor)	**I**: Dexmedetomidine (Precedex) **J**: Other (specify)

***Note**: If more bolus & continuous infusion were used, please use a supplementary form, and specify the number of the form: #___.

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ACT-TBI-CRF **Daily Data Collection** Patient ID: __ __ - __ __ __

Analgesics - Bolus					☐ No data to report
Please choose letter from table below	**Date Administered**	**Time Administered** (hh:mm)	**Route**	**Dose**	**Unit**
☐ ________________	__ __/ __ __ __/ 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ μg
☐ ________________	__ __/ __ __ __/ 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ μg
☐ ________________	__ __/ __ __ __/ 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ μg
☐ ________________	__ __/ __ __ __/ 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ μg
☐ _______________*	__ __/ __ __ __/ 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ μg

Analgesics – Continuous Infusion				☐ No data to report
Please choose letter from table below	**Date & Time Started**	**Date & Time Ended**	**Rate**	**Unit**
☐ ________________	__ __/ __ __ __/ 20 __ __ __ __ : __ __	__ __/ __ __ __/ 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ ________________	__ __/ __ __ __/ 20 __ __ __ __ : __ __	__ __/ __ __ __/ 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ ________________	__ __/ __ __ __/ 20 __ __ __ __ : __ __	__ __/ __ __ __/ 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ ________________	__ __/ __ __ __/ 20 __ __ __ __ : __ __	__ __/ __ __ __/ 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ _______________*	__ __/ __ __ __/ 20 __ __ __ __ : __ __	__ __/ __ __ __/ 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___

Table: Options for Analgesics		
A: Morphine	**C**: Remifentanyl (Ultiva)	**G**: Hydromorphone
B: Fentanyl	**D**: Sufentanil (Sufenta)	**H**: Other (specify)

***Note**: If more bolus & continuous infusion were used, please use a supplementary form, and specify the number of the form: #___.

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ACT-TBI-CRF **Daily Data Collection** Patient ID: __ __ - __ __ __

Anti-psychotics - Bolus					☐ No data to report
Please choose letter from table below	**Date Administered**	**Time Administered** (hh:mm)	**Route**	**Dose**	**Unit**
☐ ________________	__ __ / __ __ __ / 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ ________________	__ __ / __ __ __ / 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ ________________	__ __ / __ __ __ / 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ ________________	__ __ / __ __ __ / 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ ______________*	__ __ / __ __ __ / 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg

Anti-psychotics – Continuous Infusion				☐ No data to report
Please choose letter from table below	**Date & Time Started**	**Date & Time Ended**	**Rate**	**Unit**
☐ ________________	__ __ / __ __ __ / 20 __ __ __ __ : __ __	__ __ / __ __ __ / 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ ________________	__ __ / __ __ __ / 20 __ __ __ __ : __ __	__ __ / __ __ __ / 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ ________________	__ __ / __ __ __ / 20 __ __ __ __ : __ __	__ __ / __ __ __ / 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ ________________	__ __ / __ __ __ / 20 __ __ __ __ : __ __	__ __ / __ __ __ / 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ ______________*	__ __ / __ __ __ / 20 __ __ __ __ : __ __	__ __ / __ __ __ / 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___

Table: Options for Anti-psychotics		
A: Haloperidol (Haldol) **B**: Risperdone (Risperdal)	**C**: Quetiapine (Seroquel) **D**: Olanzapine (Zyprexa)	**G**: Other (specify)

***Note**: If more bolus & continuous infusion were used, please use a supplementary form, and specify the number of the form: #___

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ACT-TBI-CRF **Daily Data Collection** Patient ID: __ __ - __ __ __

Barbiturates- Bolus					☐ No data to report
Please choose letter from table below	**Date Administered**	**Time Administered** (hh:mm)	**Route**	**Dose**	**Unit**
☐ ______________	__ __/ __ __ __/ 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ μg
☐ ______________	__ __/ __ __ __/ 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ μg
☐ ______________	__ __/ __ __ __/ 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ μg
☐ ______________	__ __/ __ __ __/ 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ μg
☐ ______________*	__ __/ __ __ __/ 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ μg

Barbiturates – Continuous Infusion				☐ No data to report
Please choose letter from table below	**Date & Time Started**	**Date & Time Ended**	**Rate**	**Unit**
☐ ______________	__ __/ __ __ __/ 20 __ __ __ __ : __ __	__ __/ __ __ __/ 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ ______________	__ __/ __ __ __/ 20 __ __ __ __ : __ __	__ __/ __ __ __/ 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ ______________	__ __/ __ __ __/ 20 __ __ __ __ : __ __	__ __/ __ __ __/ 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ ______________	__ __/ __ __ __/ 20 __ __ __ __ : __ __	__ __/ __ __ __/ 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___
☐ ______________*	__ __/ __ __ __/ 20 __ __ __ __ : __ __	__ __/ __ __ __/ 20 __ __ __ __ : __ __	______	______ If mL/h or mL/min, provide concentration: ___

Table: Options for Barbiturates	
A: Pentobarbital (Nembutal)	**C**: Thiopental (Penthothal)
B: Phenobarbital (Luminal)	**D**: Other (specify)

***Note**: If more bolus & continuous infusion were used, please use a supplementary form, and specify the number of the form: #___.

Version Date: March 4, 2021

ACT-TBI-CRF **Daily Data Collection** Patient ID: __ __ - __ __ __

Vasopressors/Inotropes - Bolus					☐ No data to report
Please choose letter from table below	**Date Administered**	**Time Administered** (hh:mm)	**Route**	**Dose**	**Unit**
☐ ________________	__ __ / __ __ __ / 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ ________________	__ __ / __ __ __ / 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ ________________	__ __ / __ __ __ / 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ ________________	__ __ / __ __ __ / 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ _______________*	__ __ / __ __ __ / 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg

Vasopressors/Inotropes – Continuous Infusion				☐ No data to report
Please choose letter from table below	**Date & Time Started**	**Date & Time Ended**	**Maximum Rate (Unit)**	**Total Dose (Unit)**
☐ ________________	__ __ / __ __ __ / 20 __ __ __ __ : __ __	__ __ / __ __ __ / 20 __ __ __ __ : __ __	______ (______)° °If mL/h or mL/min, provide concentration: _____	______ (_______)
☐ ________________	__ __ / __ __ __ / 20 __ __ __ __ : __ __	__ __ / __ __ __ / 20 __ __ __ __ : __ __	______ (______)° °If mL/h or mL/min, provide concentration: _____	______ (_______)
☐ ________________	__ __ / __ __ __ / 20 __ __ __ __ : __ __	__ __ / __ __ __ / 20 __ __ __ __ : __ __	______ (______)° °If mL/h or mL/min, provide concentration: _____	______ (_______)
☐ ________________	__ __ / __ __ __ / 20 __ __ __ __ : __ __	__ __ / __ __ __ / 20 __ __ __ __ : __ __	______ (______)° °If mL/h or mL/min, provide concentration: _____	______ (_______)
☐ _______________*	__ __ / __ __ __ / 20 __ __ __ __ : __ __	__ __ / __ __ __ / 20 __ __ __ __ : __ __	______ (______)° °If mL/h or mL/min, provide concentration: _____	______ (_______)

Table: Options for Vasopressors/Inotropes			
A: Vasopressin **B**: Norepinephrine	**C**: Phenylephrine **D**: Epinephrine	**G**: Dopamine **H**: Dobutamine	**I**: Milrinone **J**: Other (specify)

***Note**: If more perfusions were used, please use a supplementary form, and specify the number of the form: #___..

Version Date: March 4, 2021

ACT-TBI-CRF **Daily Data Collection** Patient ID: __ __ - __ __ __

Other Medications - Bolus					☐ No data to report
Please choose letter from table below	**Date Administered**	**Time Administered** (hh:mm)	**Route**	**Dose**	**Unit**
☐ ________________	__ __ / __ __ __ / 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ ________________	__ __ / __ __ __ / 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ ________________	__ __ / __ __ __ / 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ ________________	__ __ / __ __ __ / 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg
☐ _______________*	__ __ / __ __ __ / 20 __ __	__ __ : __ __	☐ PO ☐ IV ☐ SC	______	☐ mg ☐ µg

Other Medications – Continuous Infusion			☐ No data to report	
Please choose letter from table below	**Date & Time Started**	**Date & Time Ended**	**Maximum Rate (Unit)**	**Total Dose (Unit)**
☐ ________________	__ __ / __ __ __ / 20 __ __ __ __ : __ __	__ __ / __ __ __ / 20 __ __ __ __ : __ __	______ (_______)° °If mL/h or mL/min, provide concentration: _____	______ (_______)
☐ ________________	__ __ / __ __ __ / 20 __ __ __ __ : __ __	__ __ / __ __ __ / 20 __ __ __ __ : __ __	______ (_______)° °If mL/h or mL/min, provide concentration: _____	______ (_______)
☐ ________________	__ __ / __ __ __ / 20 __ __ __ __ : __ __	__ __ / __ __ __ / 20 __ __ __ __ : __ __	______ (_______)° °If mL/h or mL/min, provide concentration: _____	______ (_______)
☐ ________________	__ __ / __ __ __ / 20 __ __ __ __ : __ __	__ __ / __ __ __ / 20 __ __ __ __ : __ __	______ (_______)° °If mL/h or mL/min, provide concentration: _____	______ (_______)

Version Date: March 4, 2021

ACT-TBI-CRF Daily Data Collection

Patient ID: __ __ - __ __ __

Cerebral Monitoring: □ Not applicable

Type of monitoring/device	□ Parenchymal intracranial pressure monitor (mm Hg)	□ $PbtO_2$ monitor	□ Cerebral oximetry monitoring (NIRS) (%)	□ Intraventricular pressure monitor (mm Hg)	□ Other (specify): _____
Date installed	__ __/ __ __ __/ 20__ __	__ __/ __ __ __/ 20__ __	__ __/ __ __ __/ 20__ __	__ __/ __ __ __/ 20__ __	__ __/ __ __ __/ 20__ __
Date removed	__ __/ __ __ __/ 20__ __	__ __/ __ __ __/ 20__ __	__ __/ __ __ __/ 20__ __	__ __/ __ __ __/ 20__ __	__ __/ __ __ __/ 20__ __
Record worst value of the day					
Day 1 (Day of study consent)	_____	_____	_____	_____	_____
Day 2	_____	_____	_____	_____	_____
Day 3	_____	_____	_____	_____	_____
Day 4	_____	_____	_____	_____	_____
Day 5	_____	_____	_____	_____	_____
Day 6	_____	_____	_____	_____	_____
Day 7	_____	_____	_____	_____	_____

□ Cerebral dialysis	Date installed	__ __/ __ __ __/ 20__ __	Date removed	__ __/ __ __ __/ 20__ __	
	Glucose (mmol/L)	Lactate (mmol/L)	Pyruvate (µmol/L)	Glutamate (µmol/L)	Lactate/Pyruvate ratio
Record worst value of the day					
Day 1	_____	_____	_____	_____	_____
Day 2	_____	_____	_____	_____	_____
Day 3	_____	_____	_____	_____	_____
Day 4	_____	_____	_____	_____	_____
Day 5	_____	_____	_____	_____	_____
Day 6	_____	_____	_____	_____	_____
Day 7	_____	_____	_____	_____	_____

Version Date: March 4, 2021

ACT-TBI-CRF **Outcome Measures** Patient ID: __ __ - __ __ __

6. Outcome Measures

1. Is patient alive at **Hospital discharge**?	
□ Yes, Patient alive (complete only the following questions if Yes)	
1.1. Date of ICU discharge	__ __ / __ __ __ / 20 __ __
1.2. Is patient still alive at **hospital discharge**?	□ Yes □ No If Yes, date of hospital discharge: __ __ / __ __ __ / 20 __ __
1.3. Hospital discharge location	□ Home □ Palliative Care Facility □ Other Hospital ICU □ Long-term Care Facility □ Rehabilitation Centre □ Other (specify): _____
□ No, Patient died (complete only the following questions if No)	
a. Type of death (specify date/time)	□ Cardio-circulatory arrest ___ ___ / ___ ___ ___ / 20___ ___ __ __ : __ __ □ Neurological death ___ ___ / ___ ___ ___ / 20___ ___ __ __ : __ __
b. Cause of death	
c. Withdrawal of life-sustaining therapies	□ Yes □ No
d. Was an approach made for organ donation?	□ Yes □ No, because (check all that apply): □ Unexpected death □ Physician refusal □ Lack of time □ Lack of resources □ Other (specify): _____

Version Date: March 4, 2021

ACT-TBI-CRF Outcome Measures

Patient ID: __ __ - __ __ __

2. The following questions apply only if there was an approach for organ donation	
e. Was positive consent for organ donation obtained?	□ Yes □ No
f. Who obtained consent?	□ Attending physician □ Resident □ Organ donation specialist (MD) □ Organ donation specialist (nurse) □ Organ donation organization staff □ Other (specify): _____
g. Who led the discussion?	□ Attending physician □ Resident □ Organ donation specialist (MD) □ Organ donation specialist (nurse) □ Organ donation organization staff □ Other (specify): _____
h. Who was present during the discussion? (check all that apply)	□ Parent □ Siblings □ Spouse/partner □ Friend □ Other (specify): _____
i. At what moment the family was approached (specify date/time)?	___ ___ / ___ ___ ___ / 20___ ___ __ __ : __ __ If neurological death: □ Before neurological death diagnosis □ After neurological death diagnosis
j. Who provided consent?	□ Parents □ Siblings □ Spouse/partner □ Other (specify): _____
k. Date/time consent was obtained (DD/MMM/YYY) (hh:mm)	__ __/ __ __ __ / 20 __ __ __ __ : __ __ (24 hr)
l. Did the patient donate at least one organ?	□ Yes □ No If no, specify why: _____

2. Was the patient co-enrolled in another study?		□ Yes □ No	
Complete the following questions for every co-enrolled study :			
Study Name	Study Protocol Identifier	Study Principal Investigator	Patient Identification Number (in the co-enrolled study)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Version Date: March 4, 2021

ACT-TBI-CRF **Long-term Follow-Up** Patient ID: __ __ - __ __ __

7. Long-term Follow-up

6 months follow-up	□ Not done because patient died prior to the 6 months follow-up If patient died between ICU discharge and 6 months follow-up, specify date/time & cause of death: ___ ___ / ___ ___ ___ / 20___ ___ __ __ : __ __ _____ _____ _____

A. extended Glasgow Outcome Scale (GOSe)	
Date of evaluation (DD/MMM/YYYY):	__ __ / __ __ __ /__ __ __ __
Respondent:	☐ Patient alone ☐ Relative/friend/caretaker alone ☐ Patient plus relative/friend/caretaker
Consciousness	
1. Is the person able to obey simple commands or say any words?	☐ Yes ☐ No (VS)
Independence at home	
2a. Is the assistance of another person at home essential every day for some activities of daily living?	☐ Yes ☐ No **If no: go to 3**
2b. Do you/your relative need frequent help of someone to be around at home most of tine time?	☐ Yes (lower SD) ☐ No (upper SD)
2c. Were you/was your relative independent at home before the injury?	☐ Yes ☐ No
Independence outside home	
3a. Are you/Is your relative able to shop without assistance?	☐ Yes ☐ No (upper SD)

Version Date: March 4, 2021

ACT-TBI-CRF Long-term Follow-Up Patient ID: __ __ - __ __ __

3b. Were you/was your relative able to shop without assistance before?	☐ Yes ☐ No
4a. Were you/was your relative able to travel locally without assistance?	☐ Yes ☐ No (upper SD)
4b. Were you/was your relative able to travel locally without assistance before the injury?	☐ Yes ☐ No
Work	
5a. Are you/Is your relative currently able to work (or look after others at home) to their previous capacity?	☐ Yes **If Yes: go to 6** ☐ No
5b. How restricted are you/is your relative?	
a. Reduced work capacity?	☐ a. (upper MD)
b. Able to work only in a sheltered workshop or non-competitive job or currently unable to work?	☐ b. (lower MD)
5c. Does the level of restriction represent a change in respect to the pre-brain injury situation?	☐ Yes ☐ No
Social and Leisure Activities	
6a. Are you/is your relative able to resume regular social and leisure activities outside home?	☐ Yes **If Yes: go to 7** ☐ No
6b. What is the extent of restriction on your/your relative social and leisure activities?	
a. Participate a bit less: at least half as often as before injury	☐ a. (lower GR)
b. Participate much less: less than half as often	☐ b. (upper MD)
c. Unable to participate: rarely, if ever, take part	☐ c. (lower MD)
6c. Does the extent of restriction in regular social and leisure activities outside home represent a change in respect or pre-brain injury?	☐ Yes ☐ No
Family and Friendships	
7a. Has there been family or friendship disruption due to psychological problems?	☐ Yes ☐ No **If No: go to 8**

Version Date: March 4, 2021

ACT-TBI-CRF **Long-term Follow-Up** Patient ID: __ __ - __ __ __

7b. What has been the extent of disruption or strain?	
a. Occasional – less than weekly b. Frequent – once a week or more, but not tolerable c. Constant – daily and intolerable	☐ a. (lower GR) ☐ b. (upper MD) ☐ c. (lower MD)
7c. Does the level of disruption or strain represent a change in respect to pre-brain injury situation?	☐ Yes ☐ No
Return to normal life	
8a. Are there any other current problems relating to the injury which affect daily life?	☐ Yes (lower GR) ☐ No (upper GR)
8b. If similar problems were present before the injury, have these become markedly worse?	☐ Yes ☐ No
9. What is the most important factor in outcome?	☐ a. Effects of brain injury ☐ b. Effects of illness or injury to another part of the body ☐ c. A mixture of these
GOSe Score	_____

Version Date: March 4, 2021

ACT-TBI-CRF **Long-term Follow-Up** Patient ID: __ __ - __ __ __

B. modified Rankin Scale (mRS)		
Date of evaluation (DD/MMM/YYYY):	__ __ / __ __ __ /__ __ __ __	
Respondent:	☐ Patient ☐ Spouse ☐ Son ☐ Daughter ☐ Father ☐ Mother ☐ Physical therapist ☐ Speech therapist ☐ Medical record ☐ Other individual, specify role: _____	☐ Sister ☐ Brother ☐ Other relative, specify relationship: _____ ☐ Friend ☐ Nurse ☐ Home health aide ☐ Occupational therapist ☐ Physician
5 BEDRIDDEN		
5.1 Is the person bedridden?	☐ Yes (5) ☐ No	
4 ASSISTANCE TO WALK		
4.1 Is another person's assistance essential for walking?	☐ Yes (4) ☐ No	
3 ASSISTANCE TO LOOK AFTER OWN AFFAIRS		
3.1 Is assistance ABSOLUTELY essential for preparing a simple meal?	☐ Yes (3) ☐ No	
3.2 Is assistance ABSOLUTELY essential for basic household chores?	☐ Yes (3) ☐ No	
3.3 Is assistance ABSOLUTELY essential for looking after household expenses?	☐ Yes (3) ☐ No	
3.4 Is assistance ABSOLUTELY essential for local travel?	☐ Yes (3) ☐ No	
3.5 Is assistance ABSOLUTELY essential for local shopping?	☐ Yes (3) ☐ No	
2 USUAL DUTIES AND ACTIVITIES		
Work 2.1 Has the brain injury substantially reduced (compared to preinjury status) the person's ability to work (or, for a	☐ Yes (2) ☐ No	

Version Date: March 4, 2021

ACT-TBI-CRF **Long-term Follow-Up** Patient ID: __ __ - __ __ __

student, study)?	
Family responsibilities 2.2 Has the brain injury substantially reduced (compared to preinjury status) the person's ability to look after family at home?	☐ Yes ☐ No (2)
Social & leisure activities 2.3 Has the brain injury reduced (compared to preinjury status) the person's regular free-time activities by more than one half as often?	☐ Yes ☐ No (2)
Other physical/medical condition 2.4 Are the patient's work, family, and/or social/leisure activities substantially reduced by a physical/medical condition other than the brain injury that led to trial enrollment?	☐ Yes ☐ No (2)
1 SYMPTOMS AS A RESULT OF THE BRAIN INJURY	
1.1 Spontaneously Reported Symptoms **1.1** Does the patient have any symptoms resulting from the brain injury?	☐ Yes ☐ No (1)
1.2 Symptom Checklist	
1.2.1 Does the person have difficulty reading or writing as a result of the brain injury?	☐ Yes ☐ No (1)
1.2.2 Does the person have difficulty speaking or finding the right word as a result of the brain injury?	☐ Yes ☐ No (1)
1.2.3 Does the person have problems with balance or coordination as a result of the brain injury?	☐ Yes ☐ No (1)
1.2.4 Does the person have visual problems as a result of the brain injury?	☐ Yes ☐ No (1)
1.2.5 Does the person have numbness (face, arms, legs, hands, feet) as a result of the brain injury?	☐ Yes ☐ No (1)
1.2.6 Does the person have weakness or loss of movement (face, arms, legs, hands, feet) as a result of the brain injury?	☐ Yes ☐ No (1)
1.2.7 Does the person have difficulty with swallowing as a result of the brain injury?	☐ Yes ☐ No (1)
1.2.8 Does the person have any other symptoms related to the brain injury?	☐ Yes ☐ No (1)
Rankin Grade	_____

Version Date: March 4, 2021

ACT-TBI-CRF **Violations/Deviations** Patient ID: __ __ - __ __ __

8. Violations/Deviations

1. Has there been any violations/deviations during the study?	□ Yes □ No
If Yes, complete the following questions:	
Date/time occurred	__ __ / __ __ __ / 20 __ __ __ __ : __ __
Specify violation	Violations: □ Consent not obtained in 7 days. □ Other (specify): _____
Provide the reason and all important information regarding the violation/deviation	_____ _____

Version Date: March 4, 2021

ACT-TBI-CRF **Final Protocol Disposition** Patient ID: __ __ - __ __ __

9. Final Protocol Disposition

1. How did the patient complete the study?	
□ Normal protocol completion □ Protocol completion with protocol deviation □ Study not completed □ Withdrawal of consent i. Date/time of withdrawal: ___ ___ / ___ ___ ___ / 20___ ___ ___ ___: ___ ___ ii. Reason given: _____ iii. □ with authorization to use data □ without authorization to use data	
2. Research Coordinator Signature	
Signature: _____	Date (DD/MMM/YYYY): : __ __/___ ___ ___ /20__ __
3. Investigator Signature	
Signature: _____	Date (DD/MMM/YYYY): : __ __/___ ___ ___ /20__ __

Version Date: March 4, 2021

ACT-TBI-CRF Summary of Radiology Tests Patient ID: __ __ - __ __ _

1. Summary of Radiology Tests

1. Radiology CRF		
1.1 Modalities available	CT Head	□ Yes □ No
	CTP	□ Yes □ No
	CTA	□ Yes □ No
1.2 Additional Ancillary Imaging Tests		□ Yes □ No □ CT-scan angiography □ MRI □ MRI angiography □ EEG □ Transcranial Doppler □ SSEP □ Brain CT-perfusion (other than study's CT-perfusion) □ Nuclear imaging (SPECT) □ Other. Specify: _____ Remarks on this test: __ __ ____ __ ____ __ ____ __ ____ __ ____ __ ____ __ ____ __ ____ __ _____ __ ____ __ ____ __ _____ __ ____ __ ____ ____ __ ____ __ ____ __ _____ __ ____ __ ____ __ _____ _
1.3 Any other remarks		

Version Date: October 2, 2020

ACT-TBI-CRF Summary of Radiology Tests Patient ID: __ __ - __ __ __

2. Radiology Case Report Form: Plain CT Head

Instructions

Please interpret plain CT head, when available. Base of skull fracture is to be commented upon.

If the potential cause of brain injury is not specified, please put that in Section 2.7.
If any other relevant findings on plain CT regarding potential diagnosis of brain death, please add that in remarks (Section 2.8).

Version Date: March 4, 2021

ACT-TBI-CRF Summary of Radiology Tests Patient ID: __ __ - __ __ __

2. Plain CT Head: complete this section if Yes checked for CT Head	
2.1. Date of interpretation	__ __ /__ __ __/__ __ __ __
2.2. Plain CT Test ID:	_____
2.3. Diffuse loss of Grey-white differentiation compatible with diffuse cerebral edema	□ Yes □ No
2.4. Evidence of brain herniation	□ Yes □ No
2.5. Potential cause of brain injury on imaging:	_____
2.6. Subarachnoid hemorrhage,	□ Yes □ No
2.7. Intracranial hemorrhage	□ Yes □ No
2.8. Penetrating injury	□ Yes □ No
2.9. Large ischemic stroke (> 50% of the arterial territory)	□ Yes □ No
2.10. If other, specify	_____
2.11. Base of skull fracture	□ Yes □ No □ Uncertain (bone window not available)
2.12. Remarks (any other findings)	_____

Version Date: March 4, 2021

ACT-TBI-CRF Summary of Radiology Tests Patient ID: __ __ - __ __ __

3. Radiology Case Report Form: CT Perfusion

Instructions

CTP definitions: Both **qualitative and quantitative** assessment of CTP will be done.

Qualitative assessment- CTP images will be **qualitatively** assessed by 2 Neuroradiologists.

- Matched Cerebral Blood Flow (CBF) and Cerebral Blood Volume (CBV) defect will be defined as decrease in CBV and marked decrease in CBF in the brain **consistent with established infarct**.
- Brainstem matched CBF & CBV defect will be defined as a decrease in CBV and marked decrease in CBF in the whole cross-section of the brainstem in at least 2 consecutive 5 mm slices.
- Isolated Brainstem matched CBF & CBV defect will be defined as decrease in CBV and marked decrease in CBF in the whole cross-section of the brainstem (either midbrain, mid-pons or upper medulla level), but preserved CBF and CBV in rest of the brain parenchyma.

Quantitative assessment- will be done by a research associate under the guidance of Neuroradiologist (JS). Qualitative assessment of CTP will be done by putting a large region of interest incorporating the entire cross-section of the brainstem in the area of matched CBF and CBV defect. The absolute values of CBF and CBV will be obtained at midbrain, mid-pons and upper medulla level. The final values will be taken as average from the two slices. A CBF of <20mL/100g/min and/or a CBV of < 2 mL/100g will be considered compatible with irreversible brain damage and hence brainstem death.

In patients with no imaging evidence of brain death same method of measurement of absolute values of CBF and CBV of brainstem will be used. The values will be recorded as an average of CBF and CBV obtained at midbrain, mid-pons and upper medulla level.

Version Date: March 4, 2021

ACT-TBI-CRF Summary of Radiology Tests Patient ID: __ __ - __ __ __

4. **CT-Perfusion (CTP)**: complete this section if Yes checked for CTP	
4.1. Date of interpretation	__ __ /__ __ __/__ __ __ __
4.2. CTP Test ID:	_________
4.3. Contrast opacification in extra-cranial vessels	□ Appearance □ Disappearance
4.4. Whole brain matched CBF & CBV defect	□ Yes □ No
4.5. Brainstem matched CBF & CBV defect	□ Yes □ No
4.6. Isolated Brainstem matched CBF & CBV defect	□ Yes □ No
4.7. CBF at midbrain (cerebral peduncle level) (in ml/100 gm/min)	__________ ml/100 gm/min (Normal range 38-51)
4.8. CBV at midbrain (cerebral peduncle level) (in ml/100 gm)	____________ ml/100 gm (Normal range 3.1-4.5)
4.9. CBF at mid-pons (in ml/100 gm/min)	__________ ml/100 gm/min
4.10. CBV at mid-pons (in ml/100 gm)	____________ ml/100 gm
4.11. CBF at medulla (upper medulla level) (in ml/100 gm/min)	___________ml/100 gm/min
4.12. CBV at medulla (upper medulla level) (in ml/100 gm)	____________ ml/100 gm
4.13. If isolated brain stem defect, describe the location of preserved perfusion (e.g., cerebral hemisphere, cerebellum or both)	□ Cerebral hemisphere □ Cerebellum □ Both
4.14. Remarks	__ __ __ __ __ __ __ __ __ __ __ __ __

Version Date: March 4, 2021

ACT-TBI-CRF Summary of Radiology Tests Patient ID: __ __ - __ __ __

5. Radiology Case Report Form: CT-Angiogram (CTA)

Instructions

CTA definitions: The contrast opacification of the different segments of the intracranial vessels will be analyzed by 2 Neuroradiologists. CTA will be analyzed on a 4-point, 7-point and 10-point scales on the basis of lack of opacification of the different segments of the intracranial vessels.
Lack of opacification of each of these segments gives one point resulting in "lack of opacification" scores of between 0 and 7.
4-point scale- included non-opacification of 4 vessels- cortical segments of the bilateral middle cerebral arteries (MCA) and the 2 internal cerebral veins (ICV).
7-point scale- included non-opacification in 7 vessels- bilateral M4 segment (cortical branches) of the MCA, bilateral A2 segment (pericallosal branches) of the anterior cerebral artery (ACA), bilateral ICV, and the VOG.
10-point scale- included non-opacification in 10 vessels- bilateral M4 segment (cortical branches) of the MCA, bilateral A2 segment (pericallosal branches) of the anterior cerebral artery (ACA), basilar artery, bilateral P2 segment of the posterior cerebral artery (PCA), bilateral ICV, and the VOG.
Brain death will be called on 4-point scale- when all the 4 vessels were non-opacified (i.e., the score of 4). A score less than 4 will be called "not brain dead".
Brain death will be called on 7-point scale- when all the 7 vessels were non-opacified (i.e., the score of 7). A score less than 7 will be called "not brain dead".
Brain death will be called on 10-point scale- when all the 10 vessels were non-opacified (i.e., the score of 10). A score less than 10 will be called "not brain dead".

Version Date: March 4, 2021

ACT-TBI-CRF Summary of Radiology Tests Patient ID: __ __ - __ __ __

6. CT-Angiogram (CTA) (Peak): Complete this section if Yes checked for CTA			
6.1. Date of interpretation		__ __ /__ __ __/__ __ __ __	
6.2. CTA Test ID:		_____	
6.3. CTA contrast opacification in **Peak Arterial phase**		Right	Left
	Extracranial	□ Yes □ No	□ Yes □ No
	Supraclinoid Internal Carotid Artery (ICA)	□ Yes □ No	□ Yes □ No
	Middle Cerebral Artery (MCA) (M4 or cortical segments)	□ Yes □ No	□ Yes □ No
	Anterior Cerebral Artery (ACA) (A2/3 segment)	□ Yes □ No	□ Yes □ No
	Intracranial Vertebral Artery	□ Yes □ No	□ Yes □ No
	Basilar Artery	□ Yes □ No	
	PCA-P2	□ Yes □ No	□ Yes □ No
	Internal Cerebral Vein (ICV)	□ Yes □ No	□ Yes □ No
	Vein of Galen (VOG)	□ Yes □ No	
6.4. Brain Death on CTA	4 point Scale (MCA & ICV)	□ Yes □ No	
	7 point Scale (MCA, ACA, ICV & VOG	□ Yes □ No	
	10 point Scale (MCA, ACA, BA, PCA-P2, ICV & VOG	□ Yes □ No	
6.5. Remarks			

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ACT-TBI-CRF Summary of Radiology Tests Patient ID: __ __ - __ __ __

7. CT-Angiogram (CTA) (Last Phase): Complete this section if Yes checked for CTA			
7.1. CTA contrast opacification in **last phase (at 60 sec)**		Right	Left
	Extracranial	□ Yes □ No	□ Yes □ No
	Supraclinoid Internal Carotid Artery (ICA)	□ Yes □ No	□ Yes □ No
	Middle Cerebral Artery (MCA) (M4 or cortical segments)	□ Yes □ No	□ Yes □ No
	Anterior Cerebral Artery (ACA) (A2/3 segment)	□ Yes □ No	□ Yes □ No
	Intracranial Vertebral Artery	□ Yes □ No	□ Yes □ No
	Basilar Artery	□ Yes □ No	
	PCA-P2	□ Yes □ No	□ Yes □ No
	Internal Cerebral Vein (ICV)	□ Yes □ No	□ Yes □ No
	Vein of Galen (VOG)	□ Yes □ No	
7.2. Brain Death on CTA	4 point Scale (MCA & ICV)	□ Yes □ No	
	7 point Scale (MCA, ACA, ICV & VOG	□ Yes □ No	
	10 point Scale (MCA, ACA, BA, PCA-P2, ICV & VOG	□ Yes □ No	
7.3. Remarks			

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