STUDY FORM 2: Randomisation and Outcomes

Clinician, Nurse or Nurse Practitioner responsible for patient care to complete.
Please answer ALL questions in green. Follow the instructions in peach.

Attach RANDOMISATION STICKER from Randomisation Envelope HERE to reveal allocated ORAL study medication

= “Randomisation Time”

<table>
<thead>
<tr>
<th>TIME (24hr format)</th>
<th>SAT (see table below)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>:</strong></td>
<td>Score: ___</td>
</tr>
</tbody>
</table>

Set alarm (i.e. on your phone or timer) for 1 hour from the time documented above.

MEDICATION INGESTION: N/A (circle) OR time ingested: __:__

MEDICATION REPEATED (IF spat / vomited within 5 minutes of ingestion): N/A (circle) OR time repeated: __:__

At 1 hour post Randomisation Time, regardless of whether the participant ingests oral medication or not, document time and SAT score below and complete remaining questions on page 2.

1 HOUR POST RANDOMISATION: (Re-assess patient) __:__

Score | Responsiveness | Speech
--- | --------------- | ---
+3 | Combative, violent, out of control | Continual loud outbursts
+2 | Very anxious and agitated | Loud outbursts
+1 | Anxious and restless | Normal / Talkative
0 | Responds easily to name, speaks in normal tone | Speaks normally
-1 | Responds only if name is called loudly | Slurring or prominent slowing
-2 | Physical stimulation | Few recognisable words
-3 | No response to stimulation | Nil

Document the score (numerical value) in the data-collection points above. Select the highest-ranking score.

Please answer remaining questions on Page 2
PEACHy-O: 66478_<site name> CRF_2_V1.0_09.02.2022
Please complete the following questions AT 1 hour post Randomisation Time.

Did any of the following clinical events occur within 1 hour AFTER randomisation? (Select ALL that apply below)

- [ ] None (Go to next question)
- [ ] Oxygen desaturation ≤92%
- [ ] Partial upper airway obstruction
- [ ] Apnoea (central)
- [ ] Complete upper airway obstruction
- [ ] Arrhythmia (please specify): ____________________
- [ ] Cardiac arrest
- [ ] Hypotension
- [ ] Anticholinergic side effects
- [ ] Other (please specify): ____________________
- [ ] Bradycardia
- [ ] Complete upper airway obstruction
- [ ] Extrapyramidal side effects
- [ ] Neuroleptic malignant syndrome
- [ ] Arrhythmia (please specify): ____________________
- [ ] Extrapyramidal side effects
- [ ] Complete upper airway obstruction
- [ ] Bradycardia
- [ ] Neuroleptic malignant syndrome

Time FIRST clinical events noted (24hr format): _ _ : _ _

Date (dd/mm/yyyy): _ _ / _ _ / _ _ _ _

(Document time / date of onset of ALL clinical events until time of discharge from ED in patient’s medical record and include details of management)

In your opinion, was the patient successfully sedated (see SAT table) when assessed at “Assessment Time”?  
- [ ] Yes
- [ ] No

Clinician assessment of likely cause of ASBD event?  
(Select ALL that apply)

- [ ] Mental health disorder
- [ ] Autism Spectrum Disorder
- [ ] Intellectual disability
- [ ] Substance use
- [ ] Intoxication
- [ ] Unknown
- [ ] Organic illness
- [ ] Situational crisis
- [ ] Other (please specify): ______
- [ ] ADHD

Non-pharmacological de-escalation attempts (from time of ED triage up to “Assessment Time”)?  
(Select ALL that apply)

- [ ] Verbal de-escalation
- [ ] Active listening
- [ ] Quiet room / space offered
- [ ] Food / drink offered
- [ ] Blanket / pillow offered
- [ ] Change of clothes offered
- [ ] Pain relief
- [ ] None (please detail why) ____________________
- [ ] Other (please specify) ____________________

Complete the Staff, Patient and Parent Satisfaction Surveys after “ASSESSMENT TIME” but BEFORE discharge from ED

Provide patient or parent / guardian with an Information Handout Form when the patient is no longer in a state of ASBD

DO NOT DISCARD

Return Study Forms 1, 2 and the Satisfaction Surveys to the PEaCHY-O Research Box in ED

(Ensure randomisation & patient labels are attached and Study Number is documented where indicated.)