PHARMACOLOGICAL EMERGENCY MANAGEMENT OF AGITATION IN CHILDREN AND YOUNG PEOPLE – A RANDOMISED CONTROLLED TRIAL OF INTRAMUSCULAR MEDICATION

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 IM study medication

= "Randomisation Time"

<Add medication order instructions>

PEACHy-M
IM Droperidol OR IM Olanzapine

→ Select dose based on weight (estimate acceptable)

<40kg 5mg
≥40kg 10mg

TIME (24hr format) SAT (see table below)

- - : - - Score: __ __
(Must be ≥+1 to be eligible)

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

MEDICATION ADMINISTRATION:

N/A (circle) OR time administered: _ _ : _ _ Score: __ __
(Must still be ≥+1. Enter score immediately before administering medication).

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

1 HOUR POST RANDOMISATION:
(Re-assess patient)

_ _ : _ _ Score: __ __

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

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

Please answer remaining questions on Page 2
PEACHy-M: <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
- Laryngospasm (please select airway obstruction type)
- Arrhythmia (please specify): __________________________
- Hypotension
- Bradycardia
- Neuroleptic malignant syndrome
- Apnoea (central)
- Complete upper airway obstruction
- Cardiac arrest
- Extrapyramidal side effects
- Anticholinergic side effects
- Other (please specify): __________________________

**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” when assessed at “ASSESSMENT TIME”?
- Yes
- No

Clinician assessment of likely cause of ASBD event? (Select ALL that apply)
- Mental health disorder
- Substance use
- Organic illness
- ADHD
- Autism Spectrum Disorder
- Intoxication
- Situational crisis
- Intellectual disability
- Unknown
- Other (please specify): __________

Non-pharmacological de-escalation attempts (from time of ED triage up to ASSESSMENT TIME)? (Select ALL that apply)
- Verbal de-escalation
- Food / drink offered
- Pain relief
- Other (please specify) __________________________
- Active listening
- Blanket / pillow offered
- None (please detail why) __________________________
- Quiet room / space offered
- Change of clothes offered

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 PEChY-M Research Box in ED (Ensure randomisation & patient labels are attached and Study Number is documented where indicated).