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”

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**Randomisation:**
(Time sticker applied)

**TIME (24hr format)**

**Score:**
(Must be ≥1 to be eligible)

**Medication Ingestion:**

N/A (circle) OR time ingested:

**Score:**

(Must still be ≥1. Enter score immediately before offering medication)

**Medication Repeated:**

IF spat/vomited within 5 minutes of ingestion:

N/A (circle) OR time repeated:

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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.

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**1 Hour Post Randomisation:**
(Re-assess patient)

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**Sedation and Assessment Tool (SAT)**

<table>
<thead>
<tr>
<th>Score</th>
<th>Responsiveness</th>
<th>Speech</th>
</tr>
</thead>
<tbody>
<tr>
<td>+3</td>
<td>Comitative, 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.

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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
- Complete upper airway obstruction
- Partial upper airway obstruction
- Bradycardia
- Extrapyramidal 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 (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.)