

<b>Protocol title</b>	AID-ICU Agents Intervening against Delirium in the Intensive Care Unit EudraCT no: 2017-003829-15, ClinicalTrials.gov: NCT03392376
<b>SOP name</b>	Procedure for administration and registration of escape medication
<b>Version</b>	1.0
<b>Replaces version</b>	NA
<b>Applies from</b>	27 September 2018

<b>Target population:</b> Site investigators and Research staff
<b>Responsible party:</b> Sponsor, MD, Chief physician Lone Musaeus Poulsen
<b>Created by:</b> Coordinating Investigator; Nina Christine Andersen-Ranberg
<p><b>Objective</b></p> <ul style="list-style-type: none"> <li>• To define uncontrollable delirium</li> <li>• To describe the procedure for use of escape protocol</li> <li>• To ensure uniform registration of usage of escape medication in the eCRF</li> </ul>
<p><b>Description:</b></p> <p><b>Administration of Escape Protocol</b></p> <ul style="list-style-type: none"> <li>• Uncontrollable delirium is defined as a delirious patient who cannot be sufficiently managed with the standard formula of trial medication (2,5mg haloperidol/placebo x 3 daily) and supplementary doses of trial medication (2,5mg haloperidol/placebo max x 5 daily). This may be represented as a delirious patient experiencing continuous agitation or insomnia.</li> <li>• When a patient experience uncontrollable delirium the patient's delirium can be managed with the escape protocol.</li> <li>• The escape protocol includes one or more of the following escape medications; propofol, <math>\alpha</math>2 agonists or benzodiazepines, chosen at the physicians discretion</li> <li>• The escape medications should preferably be administrated in a 'as needed' or bolus formula or a temporary increase in infusion rate of on-going infusions (e.g. Propofol, Dexmedetomidine).</li> <li>• The agent used for escape should be documented in the patient record.</li> <li>• Patients who are managed with one of the escape agents will continue to receive the intervention medication and as needed doses of haloperidol/placebo up to 20mg on a daily basis.</li> <li>• If a patient presents with an uncontrollable delirium before inclusion or while included and there is an immediate need to act (e.g. severe agitation), the clinicians are allowed to use the escape protocol before supplementary doses of trial medication tried.</li> </ul>

- Patients who have received the escape protocol before inclusion are still eligible for inclusion and this should be done as soon as possible.

**Registration of Escape protocol**

- Escape protocol is defined as medication (propofol,  $\alpha$ 2 agonist or benzodiazepines) used to treat uncontrollable delirium (e.g. agitation, insomnia).
- Administration of these agents (propofol,  $\alpha$ 2 agonist, benzodiazepines) for other purposes (e.g. intentional sedation during procedures) should not be registered as escape medication.
- Escape medication should be acknowledged as administration of these agents (propofol,  $\alpha$ 2 agonist, benzodiazepines) in a 'as needed' formula, bolus or increased infusion rate of on-going infusions of these agents.

**Responsible party for administration and registration of Escape Protocol**

Site investigators and Research staff

Approved 27 September 2018

Sponsor, Lone Musaeus Poulsen