

Protocol title	AID-ICU Agents Intervening against Delirium in the Intensive Care Unit EudraCT no: 2017-003829-15, ClinicalTrials.gov: NCT03392376
SOP name	Trial medication
Version	1.0
Replaces version	NA
Applies from	26 November 2018

Target population: Site investigators and Research staff
Responsible party: Sponsor, MD, Chief physician Lone Musaeus Poulsen
Created by: Coordinating Investigator; Nina Christine Andersen-Ranberg
<p>1. Objective</p> <ul style="list-style-type: none"> • To define pausing, re-activation and stopping criteria for trial medication • To describe how to pause and re-activate trial medication • To ensure uniform working procedures for pausing and re-activation of trial medication • To ensure uniform registration of delirium screening in the eCRF
<p>2. Description:</p> <p>2.1 Definition of pausing criteria:</p> <ul style="list-style-type: none"> • When a patient has two consecutive negative CAM-ICU or ICDSC (< 4) scores in the same day (morning assessment and evening assessment) the patient will be classified as 'delirium free' and the intervention will be paused. • When a patient meets pausing criteria, the intervention will be discontinued, but daily delirium assessment and data registration will continue. See also section 2.6. • Delirium screening must be performed by the same validated Screening tool (CAM-ICU or ICDSC). An unassessed morning or evening delirium screening cannot apply as a negative delirium screening. <p>2.2 Definition of re-activation of trial medication:</p> <ul style="list-style-type: none"> • If, hereafter, the CAM-ICU turns positive or ICDSC scores ≥ 4, the patient shall resume the allocated treatment by re-activating the trial medication promptly. <p>2.3 Definition of stopping criteria:</p> <ul style="list-style-type: none"> • The intervention period will be from randomisation until <ul style="list-style-type: none"> ○ Discharge from the ICU ○ Transferal to another ICU (not participating in AID-ICU) ○ Death in the ICU ○ 90 days post-randomisation

2.4 Description of working procedures for pausing trial medication

- When a patient fulfills pausing criteria (two consecutive negative CAM-ICU or ICDSC (< 4) scores in the same day) trial medication should be paused by the clinician on the **following morning**.
- Albeit the patient fulfils pausing criteria in the evening it is more applicable to pause trial medication the following morning, since delirium is prone to appear during night-time.
- Each morning the clinical staff shall check delirium screenings from the day before to see if trial medication should be paused.
- The morning dose of trial medication should be withheld until the delirium status of the previous day (morning+evening assessment) is reviewed.

2.5 Description of working procedures for reactivation of trial medication

- If the patient again turns delirious (CAM-ICU positive or ICDSC ≥ 4) the trial medication should be re-activated promptly.

2.6 Registration of delirium screening in the eCRF

- If a patient has a negative delirium screening in the morning and evening, but turns delirious during the night-shift, the evening assessment should be registered as positive.
- In case the patient is clinically delirious during night shift but delirium screening was not assessed, the evening assessment should be registered as 'not assessed'. This overrules an existing negative delirium screening during evening assessment.

Responsible party for administration and registration of Escape Protocol

Site investigators and Research staff

Approved 30 November 2018

Sponsor, Lone Musaeus Poulsen