Do you need help?
Call the AID-ICU Hotline
+45 9357 7750
Available 24/7
OR
aid-icu@cric.nu

Queries? Please contact:

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Agents Intervening against Delirium in the Intensive Care Unit

Information for nursing staff

Your department enrols patients in
the AID-ICU trial

The AID-ICU trial compares haloperidol and placebo for treatment of delirium in critically ill patients

The AID-ICU trial enrols 1000 patients at intensive care units in Europe

The AID-ICU trial is supported by governmental funding and is approved by all relevant authorities

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The nurse's role in AID-ICU

Delirium screening in the department

All patients admitted to the ICU should be assessed for delirium twice daily (one time during morning shift, one time during evening shift). Patients should be screened with a validated screening tool for delirium being either CAM-ICU or ICDSC. If the patient has a positive CAM-ICU or ICDSC ≥ 4, please remind the clinician to consider enrolment of the patient in the AID-ICU trial before prescribing any antipsychotics to the patient.
After enrolment and as long as the patient is admitted to the ICU, the patient should be screened for delirium twice daily.

Daily administration of trial medication

During ICU stay and as long as the patient is diagnosed with delirium, the trial medication must be given.
Standard treatment is 0.5 ml of trial medication, prescribed 3 times daily and, if necessary, additional as needed doses.
If the patient is not sufficiently managed with the standard treatment, additional as needed doses of 0.5 ml may be given to a maximum of 5 additional doses, titrated according to the level of agitation.
If further management is needed to control a patients' delirium, please see escape protocol.
The patient should receive the trial medication until the patient meets pausing or stopping criteria.

Pausing criteria
When a patient has two consecutive negative CAM-ICU or ICDSC < 4 in the **same day** (morning and evening assessment) the patient will be classified as 'delirium-free' and the trial medication (standard and as needed treatment) should be paused. Please remind the clinician to pause the trial medication in the patients' medication chart/ICU chart. If the patient again turns delirious (one positive CAM-ICU score or ICDSC ≥ 4) trial medication should be resumed. This treatment algorithm will continue until the patient meets stopping criteria.

Stopping criteria:
The intervention period lasts as long as the patient is admitted to the ICU (maximum 90 days). If the patient is discharged and readmitted to the ICU, please continue delirium screening and resume the allocated treatment if the patient turns delirious again.

Escape protocol

If the patient develops uncontrollable delirium, that cannot be sufficiently treated with trial medication and additional as needed doses (maximum 8 doses/20 mg daily), the patient may receive one or more of the following escape medications at the discretion of the clinician:

- Benzodiazepines
- Propofol-sedation
- Alfa2-agonists

The agents should be titrated until the delirium is sufficiently managed according to usual clinical practice.

Daily allocation of trial medication

The clinician randomising the patient has received the package identification number when randomising the patient. For subsequent doses, follow the guideline below

1. Visit www.cric.nu/aid-icu
2. Click 'Trial medication'
3. Login with the shared login of your department
4. Mark the patient at the list
5. Write your name in the box
6. Click 'Dispense ampule to participant'
7. Confirm
8. The ampule identification numbers will appear. One package of trial medication contains three ampules with identical ampule identification numbers.
9. Administer 0.5 ml of the medication intravenously to the patient.

A detailed manual with pictures is available at www.cric.nu/aid-icu

Please ask the clinician to prescribe the trial medication in the medication chart/ICU chart as (if possible):

1. Standard treatment: 'AID-ICU trial medication standard treatment' 0.5 ml 3 times daily

AND

2. As needed treatment: 'AID-ICU trial medication, as needed medication' 0.5 ml, maximum of 5 additional doses daily.

Information about AID-ICU

Background
Delirium among critically ill patients in the ICU is a common condition associated with increased morbidity and mortality. No evidence-based treatment exists of this condition. Haloperidol is the most frequently used agent to treat ICU-related delirium, but with no firm evidence of efficacy or safety of the intervention.
The aim of the AID-ICU trial is to assess benefits and harms of haloperidol in adult, critically ill patients with delirium in the ICU.

Methods
1000 patients with diagnosed delirium in ICUs in Europe will be randomised to receive either

- Haloperidol 2.5 mg (0.5 ml) 3 times daily and if needed additional doses of 0.5 ml haloperidol to a maximum of 20 mg/daily (5 additional doses)

or

- Placebo (0.5 ml sodium chloride 0.9 %) in the same treatment algorithm as the experimental group.

Aside from trial medication, patient management will be unaffected

Results
Our primary outcome is 'days alive out of the hospital within 90 days' (composite outcome of 90 day mortality and length of hospital stay). Secondary outcomes include days alive without delirium or coma, number of SAR/SUSARs, use of escape medication, days alive without mechanical ventilation and one-year mortality.

Funding
The trial is funded by governmental funding (Innovation Fund Denmark and the regional medicine foundation). Further funding will be sought.

The full protocol is available at www.cric.nu/aid-icu

Queries?

If you have any queries please do not hesitate to contact coordinating investigator Nina Andersen-Ranberg or Stine Estrup. See contact information at the back of this leaflet.