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 clinicians

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

Leaflet clinicians v1.0_01022018

Clinicians' role in AID-ICU

Screening

When a patient is diagnosed with delirium by a validated screening tool (CAM-ICU, ICDSC), please screen the patient for inclusion in the trial. If the patient fulfils the inclusion criteria, please screen the patient at www.cric.nu/aid-icu
Even though one or more exclusion criteria are met, we kindly ask you to complete the screening procedure.

Randomisation

Remember to obtain consent according to your national regulations before randomisation (if required).

Complete the screening procedure. If the patient fulfils the inclusion criteria and no exclusion criteria are met, you will get the opportunity to randomise the patient.
Click 'Perform randomisation'. A window with the allocated package identification number will appear. One package of trial medication contains three ampules with identification numbers identical to the package identification number.

Print or write down the package identification number.
If you lose the number, you can find it in the bottom of the screening form, in an email sent to your email address used for registration or in the trial medication system.
Prescribe the trial medication in the patient's medication chart/ICU chart as (if possible):

1. Standard treatment: 'AID-ICU trial medication standard treatment' intravenously three times daily'. **Remember to prescribe the first dose at the time for randomisation.**

AND

2. As needed (p.n.) medication: 'AID-ICU trial medication, as needed medication' To a maximum of 5 (x 0.5 ml) additional doses daily.

During the ICU stay

Delirium assessment:
All patients included in the trial are screened for delirium twice daily (once during morning shift, once during evening shift).

Trial medication
0.5 ml of trial medication is prescribed 3 times daily as standard treatment until the patient meets pausing or stopping criteria (see below).
Additional doses of trial medication (as needed doses) are available to a maximum of 5 additional doses daily and should be titrated according to the patient's level of agitation.
If further management is needed to control a patient's delirium, please see escape protocol below.

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.

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 all trial medication is paused.
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 for 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.

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 do not hesitate to contact coordinating investigator Nina Andersen-Ranberg or Stine Estrup. See contact information at the back of this leaflet.