



Place in Site Master File #9a

Instruction for the AID-ICU trial - eligibility

Inclusion criteria

- ✓ **Acute (unplanned admission) to the ICU**
- ✓ **Aged 18 years or above**
- ✓ **Diagnosed delirium with validated screening tool CAM-ICU or ICDSC**

Exclusion criteria

✗ **Contraindications to haloperidol**

- Any history of intolerance to haloperidol or additives
- Known Parkinsons disease or other extrapyramidal symptoms
- Known QTc prolongation
- History of tardive dyskinesia
- Comatose patients (non pharmacological)
- Previous ventricular arrhythmia or torsades de pointes
- Uncorrected hypokalaemia

✗ **Habitual antipsychotic medication**

Yes, if the patient have daily intake or receive prolonged release medication (any form) of any antipsychotic medication ATCN05A.

✗ **Treatment with antipsychotics in the ICU prior to inclusion**

Yes, if the patient has been treated with antipsychotics in the ICU prior to inclusion. Antipsychotic treatment (not habitual) in the general ward prior to ICU admission is not considered an exclusion criteria.

× **Permanently incompetent**

Permanently incompetent is a patient who permanently is unable to make decisions about his/hers affairs (e.g. dementia, mental retardation). The attending physician makes this judgement.

× **Delirium Assessment non applicable**

Delirium assessment is non-applicable if the patient:

- Is comatose defined by the following scales of level of consciousness: RASS -4 to -5 (RASS -3 may be considered as coma if this is the judgement of the treating physician), Ramsey sedation score 4-6, MASS 1-0, GCS < 8, RLS > 3, SAS 1-2.
- Have language barriers including foreign language where delirium assessment cannot be confidently performed by the site staff
- Patients who are deaf, blind or aphasic are also excluded

× **Withdrawal from active therapy or brain death**

× **Fertile woman with positive urine human chorionic gonadotropin (hCG) or plasma-hCG**

In fertile women (< 50 years) a negative pregnancy test have to be present before inclusion.

× **Consent according to national regulations not obtainable**

× **Patients under coercive measures (involuntary hospitalization)**

× **Patients with alcohol induced delirium (delirium tremens)**

Alcohol induced delirium/delirium tremens (ICD10: F10.4x) is defined as delirium caused by withdrawal of alcohol after persistent use of the substance. The withdrawal may be complicated by convulsions. The treating physician makes this judgement.