

Welcome to AID-ICU screening procedure

#	Question	Answer	Info	Validation and limits	Further comments for data manager
Patient identification					
S1	National identification number		<p>For Danish sites: CPR number (10 digits without dash). If the patient has a fictive CPR number, please use the letter D as a prefix, e.g. D1002550JHO (D followed by 10 characters). If an unknown patient is identified, you have the option to change the fictive CPR number to the correct CPR number.</p> <p>For non-Danish sites: The national identification number is some identification string which may consist of both numbers and letters. The system uses this identification to check if this patient has previously been screened in AID-ICU.</p>	Required for DK sites	<p>Denmark: RED WARNING A participant with identical CPR number has previously been enrolled in the AID-ICU trial and cannot be randomised again. If the participant was enrolled at your department, please readmit the patient in the system. If not please contact the coordinating centre for transferal of the patient in the system.</p> <p>contact aid-icu@cric.nu or +45 9357 7750</p> <p>WARNING if CPR is invalid Format of CPR is not correct. It should be 10 digits long. If a fictive CPR is entered, please use the prefix 'D' (capital D) followed by 10 characters. See 'info'.</p> <p>Other countries: RED WARNING: (validating on enrolled</p>

				<p>patients only) The trial participant below with the same national identification number (NIN) has previously been enrolled in the SUP-ICU trial. If the trial participant below is not identical to the one you are trying to screen, please increase the serial number by 1 (e.g. change 01 to 02). If the trial participant has been enrolled previously, please readmit the patient in the system. For further information please</p> <p>contact aid-icu@cric.nu or +45 9357 7750</p> <p>YELLOW WARNING: (Validating on enrolled patients in the same country with the same birthday) The trial participants listed below are potentially identical with the one you are trying to screen. Please check the list below. If the trial participant you are trying to screen is NOT identical to any of the participants below, please press accept to continue. If the patient has been enrolled previously, please readmit the patient in the system. For further information please</p>
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					<p>contact aid-icu@cric.nu or +45 9357 7750</p> <p>Warning if NIN of an excluded patient is entered again: A patient with the same NIN has previously been excluded. If you want to screen the patient again, please press accept. For further information please</p> <p>contact aid-icu@cric.nu or +45 9357 7750</p>
Inclusion criteria					
S2	Does the patient have delirium?	<input type="checkbox"/> YES <input type="checkbox"/> NO	YES, if the patient has a positive CAM-ICU score or a score ≥ 4 in the ICDSC.	Required	
S3	Is the patient ≥ 18 years old?	<input type="checkbox"/> YES <input type="checkbox"/> NO		Required	
S4	Was the patient acutely admitted to the ICU?	<input type="checkbox"/> YES <input type="checkbox"/> NO	<p>Acute admission: a non-planned ICU admission.</p> <p>It does not include:</p> <ul style="list-style-type: none"> Planned recovery after surgery or similar planned admission Admission to semi intensive care, intermediate intensive care or similar bed. 	Required	

Exclusion criteria

Please ensure that the patient does not fulfil any criteria below at ICU admission

S5	Does the patient have any contraindications to receive haloperidol?	<input type="checkbox"/> YES <input type="checkbox"/> NO	<p>YES, if any of the following:</p> <ul style="list-style-type: none"> - Any history of intolerance to haloperidol or additives - Known Parkinson's disease or other extrapyramidal symptoms - Known QTc prolongation - History of tardive dyskinesia - Comatose patients (non-pharmacological). Coma is defined by the following scales of level of consciousness: GCS \leq 8, RLS $>$ 3, SAS 1-2. - History of ventricular arrhythmia or torsades de pointes - Uncorrected hypokalaemia (defined as a P-potassium level lower than that defined by the site for which 'no corrective action' has been taken) 	Required	
S6	Does the patient receive habitual treatment with antipsychotic medication?	<input type="checkbox"/> YES <input type="checkbox"/> NO	<p>YES, if the patient has daily intake or receives prolonged release medication (any form) prior to ICU admission (e.g. haloperidol, chlorprothixen, flupentixol,</p>	Required	

			levomepromazin, loxapin, melperon, perfenazin, periciazin, pimozid, prochlorperazin, zuclopenthixol, pipamperon, sulpirid, amisulprid, aripiprazol, asenapin, clozapine, lurasidon, paliperidon, quetiapin, risperidon, sertindol, ziprasidon).		
S7	Has the patient received antipsychotics in the ICU prior to screening?	<input type="checkbox"/> YES <input type="checkbox"/> NO	YES, if the patient has been treated with antipsychotics in the ICU before inclusion. Treatment with antipsychotics in the hospital prior to ICU admission is not an exclusion criterion.	Required	
S8	Is the patient permanently incompetent?	<input type="checkbox"/> YES <input type="checkbox"/> NO	YES, if the patient is permanently unable to make decisions about his/her affairs (e.g. dementia, mental retardation). Patients may or may not have a legal guardian. The attending doctor makes this assessment.	Required	
S9	Is delirium assessment non-applicable?	<input type="checkbox"/> YES <input type="checkbox"/> NO	YES, if any of the following: <ul style="list-style-type: none"> - Language barriers - Blind patient - Deaf patient 	Required	
S10	Is the patient withdrawn from active therapy or brain dead?	<input type="checkbox"/> YES <input type="checkbox"/> NO	Patients where withdrawal from therapy or brain death	Required	

			is documented in the patient's charts.		
S11	Is the patient pregnant?	<input type="checkbox"/> YES <input type="checkbox"/> NO	In fertile women (< 50 years) a negative urin-hCG or plasma-hCG is needed. Please make sure this is documented in patient or lab charts.	Required	
S12	Consent unobtainable according to national regulations?	<input type="checkbox"/> YES <input type="checkbox"/> NO	YES, if the clinician or investigator is unable to obtain necessary consent before or after inclusion of the patient according to the national regulations.	Required	
S13	Is the patient under coercive measures by regulatory authorities?	<input type="checkbox"/> YES <input type="checkbox"/> NO	YES, if the patient is under involuntary hospitalisation by regulatory authorities.	Required	
S14	Does the patient have alcohol-induced delirium (delirium tremens)?	<input type="checkbox"/> YES <input type="checkbox"/> NO	Alcohol induced delirium is defined as delirium caused by withdrawal of alcohol after persistent use of the substance.	Required	

If YES to S2-S4 and NO to S5-S14:

Trial participant is eligible for inclusion in the AID-ICU Trial.

Fill in name, choose delirium subtype below and then click the 'Perform randomisation' button.

If YES to S2-S4 and YES to one or more of S5-S14:

The patient fulfils one or more exclusion criteria.

Thus, this patient cannot be randomised in the AID-ICU trial.

If this is correct, click 'Submit' button to exclude the patient.

If NO to one or more of S2-S4

**The inclusion criteria are not fulfilled.
Thus, the patient cannot be randomised in the AID-ICU trial.
If this is correct, click 'Submit' button to exclude the patient.**

**If YES to all inclusion criteria and NO to all exclusion criteria,
the patient can be included in the AID-ICU trial**

Stratification Variables

S15	Patient name	_____ <input type="checkbox"/> Unknown at admission	If the participant is currently unknown, click the "Unknown at admission checkbox"	Required	
S16	Delirium motor subtype	<input type="checkbox"/> Hypo <input type="checkbox"/> Hyper	<p>Defined as:</p> <ul style="list-style-type: none"> Hypo: if the patient is considered HYPOactive and is positive for delirium on this day (e.g. lying still with open eyes and no clear contact) Hyper: if the patient is considered HYPERactive and is positive for delirium on this day (e.g. agitated and non-corporative, 		

			pulling tubes and/or catheters)		
S17	Site			Required	Automatically generated in the eCRF
S18	Participant randomised to	XXXXX		Required	Automatically generated in the eCRF
S19	Randomisation timestamp	YYYY:MM:DD HH:MM:SS		Required	Automatically generated in the eCRF

Info box

Randomisation complete

NIN: xxxxxxxxxxxx

Name: xxx

Participant ID: DKxxxxx

Participant randomised to medicine pack:

XXXXX