Place in Site Master File #9

Instructions for the AID-ICU trial - screening and randomisation

Please screen all adults meeting the inclusion criteria (i.e. patients admitted acutely to the ICU and diagnosed with delirium) to assess their eligibility for inclusion in AID-ICU.

Re-assess the inclusion criteria during ICU stay in patients not meeting the criteria at ICU admission.

A screening log is maintained to monitor patient recruitment at each site and will enable a description of the patient population from which eligible patients have been enrolled. All patients will be allocated a site-specific trial participant ID when initiating the screening procedure.

Questions and uncertainties may be answered by keeping the cursor on the [info] next to each question in the eCRF.

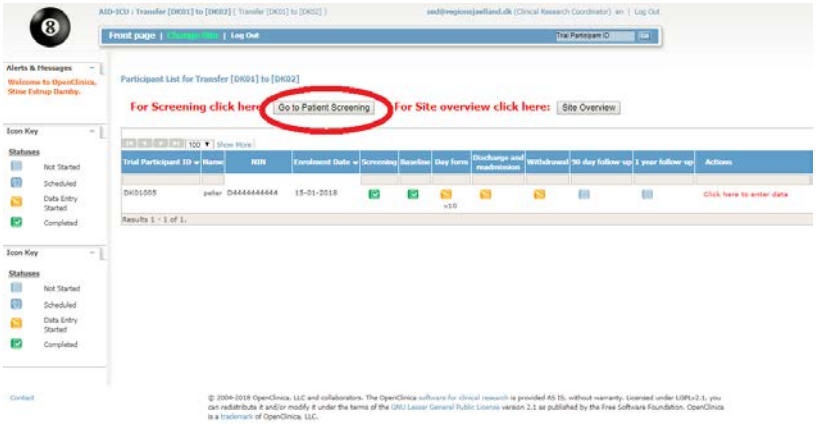
1. Go to www.cric.nu/aid-icu

Click the eCRF link to 'Screen, randomise and enter data'

2. Login to the eCRF with your personal login.

If you have not received your login, please send an email to aid.icu@cric.nu

3. Click the '*Go to patient screening'* button.



4. A national identification number (NIN) is needed to help identifying the patient.

Danish sites:

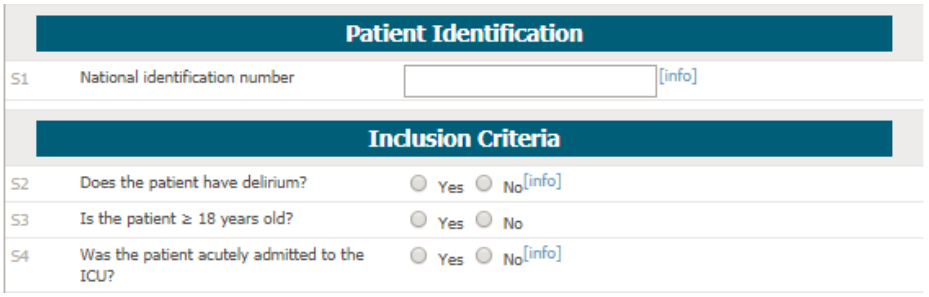
Enter the CPR number in Danish participants

If a fictive CPR number has been constructed **use the letter D** as prefix to override the check of a valid CPR number. (e.g. D1010501234)

In all other countries, a NIN must be constructed

NIN is a unique number identifying the patient and will be checked by the system to make sure the same patient is not randomised more than once. In some countries, other rules will apply. Please consult your national investigator in case of uncertainties. The NIN consists of:

- date of birth (ddmmyy)
- a site identification (automatically generated)
- a serial number. Enter 01.



If a warning appears, please check that the patient has not previously been enrolled.

WARNINGS: two types of warnings are possible:

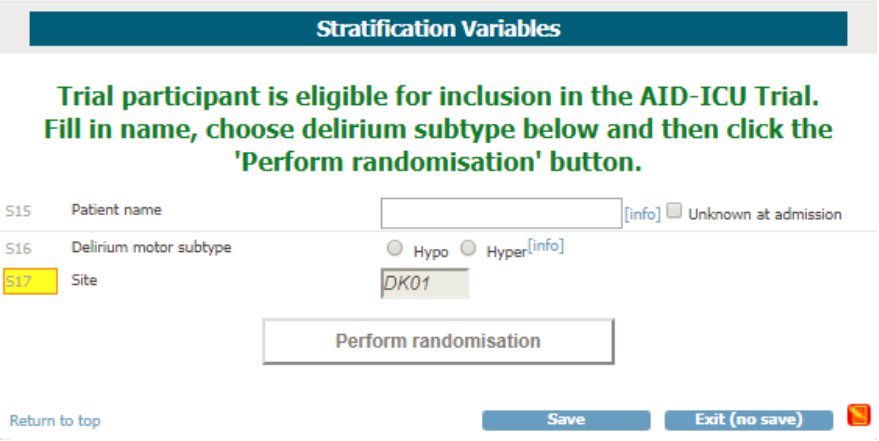
Red warning: The NIN is completely identical with a previously constructed NIN. If it is NOT the same patient, **please change the serial number to 02.**

Yellow warning: The NIN is partly identical to a previously constructed NIN. If the name of the patient does not appear on the list shown, please press '**accept'** and continue.

5. Complete the screening form.

Note that fertile women (women < 50 years) must have a negative pregnancy test before screening and that consent **always** has to be obtained according to national regulations.

When the form is complete, the text in the randomisation window will change to either green (eligible) or red (not eligible).



6. Make sure all answers are correct.

If the patient is eligible for randomisation, enter the name of the patient. If the patients name is unknown at time of randomisation, the name and correct birthdate can be added later during the trial. Entering the correct name helps you identify the patient when allocating trial medication and entering data.

Question S16 is a stratification variable and must be answered before randomisation is possible.

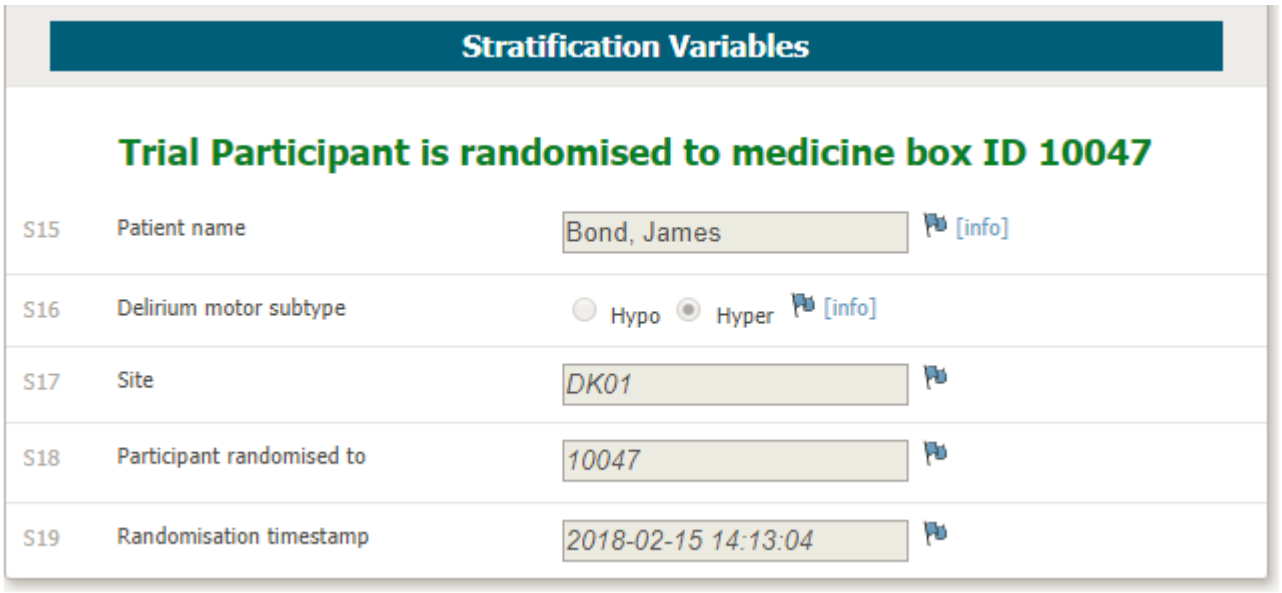
7. When the form is complete the 

- button will be active.

Clicking the button will randomise the patient and a pack identification number will appear.

You can save/find the pack identification number by:

- printing the message
- opening the email sent to the email account used when logging in
- opening the medication distribution system
- opening the screening form. The pack identification will be visible in the randomisation window (see next page). In the screening form you can also update the name later.



8. Prescribe the trial medication for the patient three times daily in your medical chart/ICU chart

9. Administer the trial medication by administering 0.5 ml of trial medication (see the trial document 'Trial medication')