



Place in Site Master File #9

Instruction for the SUP-ICU trial - screening and randomisation

Please screen all adults meeting the inclusion criteria (admitted acutely to the ICU with one or more risk factors for GI bleeding) to assess their eligibility for inclusion in SUP-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.

1. Go to www.sup-icu.com

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

Stress Ulcer Prophylaxis in the Intensive Care Unit
An international critical care research programme

Home Research programme information Organization Funding Publications Contact

Home SUP-ICU trial (not yet recruiting)

Screen, randomise, and enter data
Do you want to screen, randomise or enter data?
→ Click here

Trial medication
Do you want to dispense trial medication?
→ Click here

Trial documents
Protocol, trial procedures, Site Master File etc.
→ Click here

2. Login to the eCRF with your personal login. If you have not received your login, please send an email to contact@sup-icu.com

Stress Ulcer Prophylaxis in the Intensive Care Unit
S
ICU
P

Login

User Name

Password

Login Forgot Password?

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

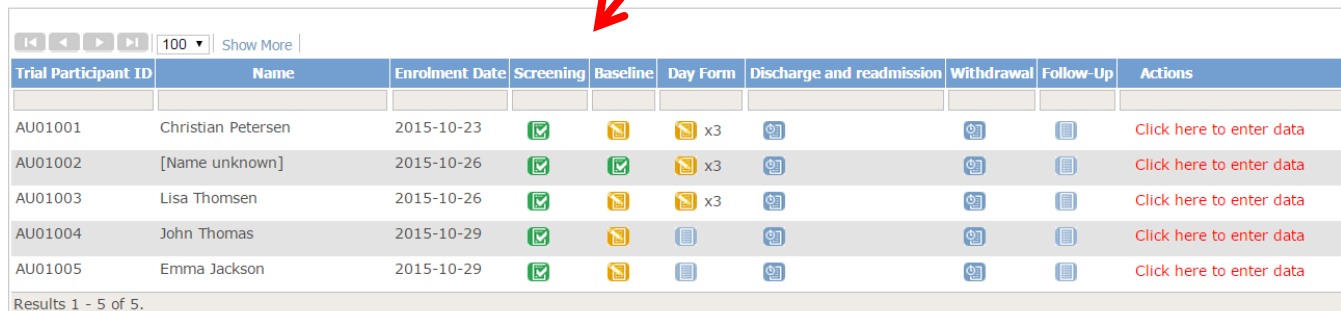
Participant List for Canberra, Australia

For Screening click here:

Go to Patient Screening

For Site overview click here:

Site Overview



The screenshot shows a table with the following columns: Trial Participant ID, Name, Enrolment Date, Screening, Baseline, Day Form, Discharge and readmission, Withdrawal, Follow-Up, and Actions. The table contains five rows of participant data. A red arrow points from the text 'For Site overview click here:' to the 'Go to Patient Screening' button.

Trial Participant ID	Name	Enrolment Date	Screening	Baseline	Day Form	Discharge and readmission	Withdrawal	Follow-Up	Actions
AU01001	Christian Petersen	2015-10-23	✓	📄	📄 x3	📄	📄	📄	Click here to enter data
AU01002	[Name unknown]	2015-10-26	✓	✓	📄 x3	📄	📄	📄	Click here to enter data
AU01003	Lisa Thomsen	2015-10-26	✓	📄	📄 x3	📄	📄	📄	Click here to enter data
AU01004	John Thomas	2015-10-29	✓	📄	📄	📄	📄	📄	Click here to enter data
AU01005	Emma Jackson	2015-10-29	✓	📄	📄	📄	📄	📄	Click here to enter data

Results 1 - 5 of 5.

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 a prefix to override the check of a valid CPR number.

In all other countries, NIN has to 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. The NIN consists of:

- date of birth (ddmmyy) (for Switzerland 0101+year)
- a site identifier (automatically generated)
- a serial number. Enter 01.

If a warning appears (see below), 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.

[Exit \(no save\)](#)

SCREENING FORM

PATIENT IDENTIFICATION

S1 National identification number [\[info\]](#)

Date of birth (ddmmyy) Site ID Serial

5. Complete the screening form.

Note that fertile women have to have a negative pregnancy test before screening and that consent according to national regulations **always** has to be obtained.

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

RANDOMISATION


Trial participant is eligible for inclusion in SUP-ICU Trial.
Fill in name and stratification below and click the
'Perform randomisation' button.

S21 Name of the patient [\[info\]](#) Unknown at admission

S22 Haematological malignancy? Yes No [\[info\]](#)

S23 Site

[Perform randomisation](#)

[Return to top](#) [Save](#) [Exit \(no save\)](#) 

6. Make sure all answers are correct.

If the patient is eligible for randomisation enter the name of the patient (Switzerland: initials only). If unknown the name and correct birthdate can be added later during the trial. This will help you identify the patient when allocating trial medication and entering data.

Question S22 is a stratification variable and has to be answered before randomisation.

7. When the form is complete 'Perform randomisation' will be active. Click the button. The patient has now been randomised and a vial identifier number will be highlighted.



You can save/find the vial identifier number by

- printing the message
- opening the email send to the email account used when signing up
- opening the medication distribution system
- opening the screening form. The vial identifier will be visible in the randomisation window

RANDOMISATION

Trial Participant is randomised to vial identifier number 10528

S21	Name of the patient	Lisa Thomsen [info]
S22	Haematological malignancy?	<input type="radio"/> Yes <input checked="" type="radio"/> No [info]
S23	Site	Canberra, Australia
S24	Vial identifier number	10528
S25	Randomisation timestamp	2015-10-26 19:28:02

Return to top Exit (no save)

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

9. Administer the trial medication by adding 10 ml of sodium chloride 0.9% to the vial (see the trial document 'Trial medication')