



Place in Site Master File #9

Instructions for the SUP-ICU trial – trial medication

This manual describes the use of the Medication Dispensing System and administration of the trial medication in the SUP-ICU trial

Medication Dispensing System

The vial identifier number of the first vial will be allocated during the randomisation procedure. You can always find the previously allocated vial identifier numbers in the Medication Dispensing System (see bullet 4 below).

Every day a new vial identifier number has to be allocated to the patient.

1. Visit www.sup-icu.com
2. Click 'Trial medication'

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

3. Login with the shared login of your department

4. A list of enrolled patients at your department will appear

Welcome to the Medication Dispensing System for SUP-ICU

You are logged in to site Copenhagen, Denmark [DK01]

Choose participant on site

Participant ID	NIN	Name	Randomisation timestamp
DK01003	D1203561234	Jane Carlson	16-11-2015 09:18
DK01002	D1205681245	Michael Thomsom	16-11-2015 09:17
DK01001	D1203521208	Mark Jakobsen	16-11-2015 09:16

5. Mark the relevant patient in the list. Previous vial identifier numbers will be shown at the bottom of the window.

Welcome to the Medication Dispensing System for SUP-ICU

You are logged in to site Copenhagen, Denmark [DK01]

Choose participant on site

Participant ID	NIN	Name	Randomisation timestamp
DK01003	D1203561234	Jane Carlson	16-11-2015 09:18
DK01002	D1205681245	Michael Thomsom	16-11-2015 09:17
DK01001	D1203521208	Mark Jakobsen	16-11-2015 09:16

Enter your name: Marie Berg

Dispense vial to participant

Participant's previously dispensed vials

#	Identifier number	Dispense timestamp	Dispensator	Comments	Add Comment
2	10100	16-11-2015 09:23	Marie Berg	2015-11-16 09:23:04 [Reason for premature vial dispense]: 2nd vial	Add comment
1	10148	16-11-2015 09:18			Add comment

Print previously dispensed vials

6. Enter your name in the box

7. Press 'Dispense vial to patient'

Welcome to the Medication Dispensing System for SUP-ICU

You are logged in to site Copenhagen, Denmark [DK01]

Choose participant on site

Participant ID	NIN	Name	Randomisation timestamp
DK01003	D1203561234	Jane Carlson	16-11-2015 09:18
DK01002	D1205681245	Michael Thomsom	16-11-2015 09:17
DK01001	D1203521208	Mark Jakobsen	16-11-2015 09:16

Enter your name: Marie Berg

Dispense vial to participant

8. If data are correct, confirm by clicking 'Yes'

Confirmation

You are about to dispense a vial for trial participant

Participant ID: DK01003
NIN: D1203561234
Name: Jane Carlson

Last vial was dispensed on 16-11-2015 09:18
 Your name: Marie Berg

Would you like to continue?

9. The vial identifier number will appear
 You have the option to print the number

Result

Vial with identifier number **10100**
 has been assigned to trial participant

Participant ID: DK01003
NIN: D1203561234
Name: Jane Carlson

If you experience a problem with the vial or the medication administration, please use the 'Add comment' button in the right side of the list of previously dispensed vial identifier numbers. If necessary, run through the procedure again to allocate a new vial identifier number.

Welcome to the Medication Dispensing System for SUP-ICU
 You are logged in to site Copenhagen, Denmark [DK01]

Choose participant on site

Participant ID	NIN	Name	Randomisation timestamp
DK01003	D1203561234	Jane Carlson	16-11-2015 09:18
DK01002	D1205681245	Michael Thomson	16-11-2015 09:17
DK01001	D1203521208	Mark Jakobsen	16-11-2015 09:16

Enter your name: Marie Berg

Participant's previously dispensed vials

#	Identifier number	Dispense timestamp	Dispensator	Comments	Add Comment
2	10100	16-11-2015 09:23	Marie Berg	2015-11-16 09:23:04 [Reason for premature vial dispense]: 2nd vial	<input type="button" value="Add comment"/>
1	10148	16-11-2015 09:18			<input type="button" value="Add comment"/>

First and second dose:

If there are less than 20 hours between two medication allocations a warning will appear and you have to write a reason for this (see below). This may happen if a patient is randomised prior to the normal time of medication administration in your department. Please write '2nd vial' or similar sentence:

Warning

Last vial with identifier number 10148 was dispensed on **16-11-2015 09:18**.
 Please state reason why new dispensation is required less than 20 hours after last dispensation.

Reason:

Handling of trial medication

Patients will be randomised to receive:

Active drug: Pantoprazole 40 mg x 1 per day added 10 ml of sodium chloride 0.9%

OR

Placebo: Sterile air filled vial x 1 per day added 10 ml of sodium chloride 0.9%

- The trial medication is reconstituted to solution and administered as an injection once daily until discharge from ICU or death.
- Aside from trial medication patient management will be otherwise unaffected
- Trial medication must be kept at room temperature (0-25°C) and protected from sunshine
- Once reconstituted the trial medication is stable for 12 hours
- Trial medication should be prescribed in the patient's medication chart or ICU chart as 'SUP-ICU trial medication once daily' or similar

Instructions for preparation of trial medication

- After the randomisation procedure the vial identifier number of the first vial will be displayed on the screen
- Each day a new vial identifier number has to be provided at the webpage (please see above)
- Do not tamper or remove the blinding label of the vial
- The identifier number of the vial has to match the identifier number provided to the patient at the web page for this day
- If damage to the vial is suspected do not use the vial. Allocate a new vial to the patient in the Medication Dispensing System

Preparation:

1. Remove the yellow cap. If the yellow cap is missing do not use the vial! Allocate a new vial for the patient
2. Inject 10 ml of sodium chloride 0.9% into the vial
3. Agitate gently for a few seconds
4. Aspirate the content into the same syringe. Make sure all 10 ml is aspirated
5. Inspect the solution in the syringe for irregularities. The trial medication should be colourless.
6. Administer the trial medication via a dedicated venous catheter as an injection

Do not use the vial if irregularities are detected.

Contact the SUP-ICU hotline: +45 3545 7450

Disposal of trial medication

1. Un-planned disposal of trial medication not accounted for in the Medication Dispensing System

- a. **If** you suspect in any way that one or more vials are damaged, the vial identifier number is unclear, or you have experienced inappropriate or compromising handling of the medicine according to the guidelines for handling, storing and use of the medicine,
- b. **then** dispose the vials in the drug waste containers normally used to dispose proton pump inhibitors such as Pantoprazole,
- c. **state the vial identifier number(s) disposed and sign** the Drug Disposal Form (Trial documents, Site Master File #10) for accountability reasons, and
- d. **e-mail** the signed Drug Disposal Form to contact@cric.nu.

2. Sponsor requested disposal of the trial medication

- a. **If** your receive a written instruction by e-mail from Sponsor requesting disposal of specified vial identifier numbers, or the remaining storage of trial medication as a bulk, as should be the case at the end of the trial,
- b. **then** dispose the vials in the drug waste containers normally used to dispose proton pump inhibitors such as Pantoprazole,
- c. **state the vial identifier number(s) disposed and sign** the Drug Disposal Form (Trial documents, Site Master File #10) for accountability reasons, and
- d. **e-mail** the signed Drug Disposal Form to contact@cric.nu.