

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'



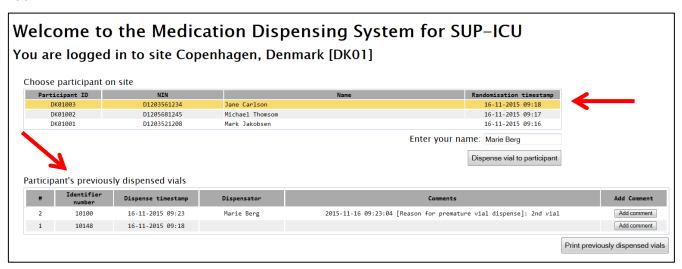
3. Login with the shared login of your department



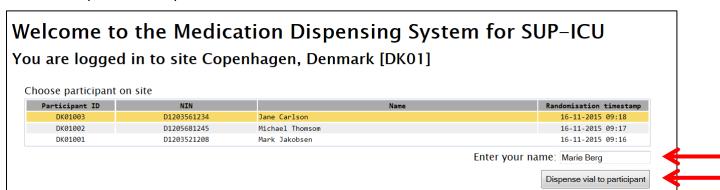
4. A list of enrolled patients at your department will appear

Welcome to the Medication Dispensing System for SUP-ICU You are logged in to site Copenhagen, Denmark [DK01] Choose participant on site Participant ID DK01003 D1203561234 Jane Carlson 16-11-2015 09:18 DK01002 D1205681245 16-11-2015 09:17 Michael Thomson D1203521208 DK01001 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.



- 6. Enter your name in the box
- 7. Press 'Dispense vial to patient'

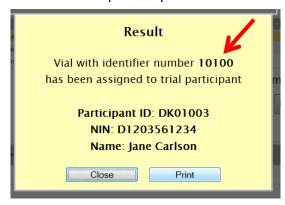




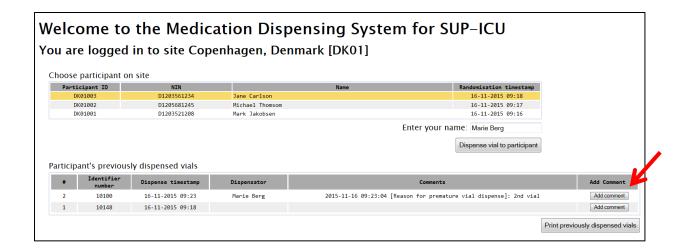
8. If data are correct, confirm by clicking 'Yes'



The vial identifier number will appearYou have the option to print the number

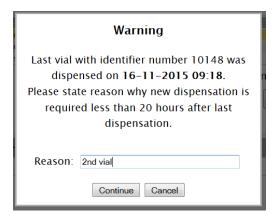


If you experience a problem with the vial or the medication administration, please use the 'Add comment' button in the right side of the list of previously dispensed vial identifier numbers. If necessary, run through the procedure again to allocate a new vial identifier number.



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:



CRIC • Blegdamsvej 9, 7812 • 2100 Copenhagen Ø • +45 35 45 71 67 • contact@cric.nu • www.cric.nu



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 supected 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



Page 4 of 5

Disposal of trial medication

Un-planned disposal of trial medication <u>not</u> 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 compromizing 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.

