

Agents Intervening against Delirium in the Intensive Care Unit (AID-ICU) 8 February 2018, version 1.0

Instructions for the AID-ICU trial - trial medication

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

Medication Dispensing System

At randomisation, the first trial medication package enclosing three identical ampules will be allocated to the randomised patient. This pack identification number, which is also found on the three ampules within it, will be sent to the email of the person who performed the randomisation. You can always find previously allocated pack identification numbers in the Medication Dispensing System, including the package automatically dispensed at randomisation.

When the first three ampules of trial medication are used, a new trial medication package needs to be allocated to the patient. The frequency of dispensing trial medication is dependent of the patient's need of additional as needed doses of trial medication. Three daily doses and, if necessary, 5 additional as needed doses are available each day. Allocated ampules that are not broken should be saved for administration on the next day.

1. Visit www.cric.nu/aid-icu

PROTECTED: AID-ICU

Modified: February 8, 2018 at 12:44 pm



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Screen, randomise and enter data



Trial medication



Trial documents

2. Click 'Trial medication' to enter the medication module

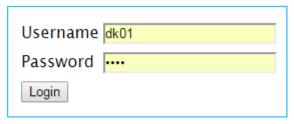


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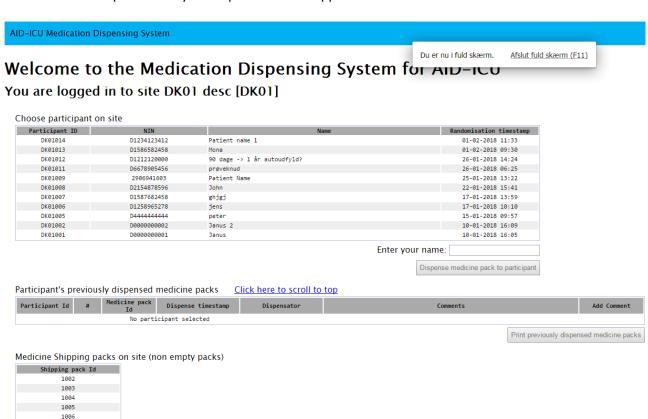
3. Log on with the shared login of your department

AID-ICU Medication Dispensing System

Log In



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





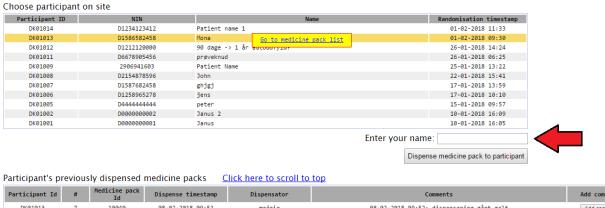
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5. Mark the relevant patient in the list. A list of the identification numbers of previously dispensed packages to that patient will appear at the bottom of the page, including the automatically dispensed package from the time of randomization.

AID-ICU Medication Dispensing System

Welcome to the Medication Dispensing System for AID-ICU

You are logged in to site DK01 desc [DK01]



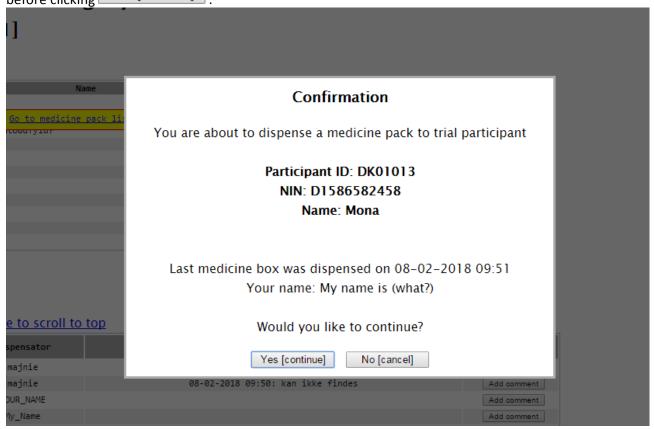
| Participant Id | # | Medicine pack Id | Dispense timestamp | Dispensator | Comments | Add comment |
|----------------|---|---------------------|--------------------|-------------|---|-------------|
| DK01013 | 7 | 10040 | 08-02-2018 09:51 | majnie | 08-02-2018 09:52: dispensering gået galt | Add commer |
| DK01013 | 6 | 10036 | 08-02-2018 09:42 | majnie | 08-02-2018 09:50: kan ikke findes | Add commer |
| DK01013 | 5 | 10035 | 04-02-2018 17:25 | YOUR_NAME | | Add commer |
| DK01013 | 4 | 10034 | 04-02-2018 14:47 | My_Name | | Add commer |
| DK01013 | 3 | 10032 | 02-02-2018 13:18 | Jens | | Add commer |
| DK01013 | 2 | 10029 | 01-02-2018 14:15 | rrtuysrtys | | Add comme |
| DK01013 | 1 | 10015 | 01-02-2018 09:30 | System | 01-02-2018 09:30: Dispensed by randomisation system | Add commer |

6. If you wish to dispense a pack of medicine (containing 3 ampules/doses) to the selected patient, enter your name and press Dispense medicine pack to participant.



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7. You will be asked to confirm the dispensation of trial medication. Please ensure that all data are correct before clicking Yes [continue].



If you experience a problem with an ampule or package, if the ampule is broken or any other issues during dispensation or administration, please add a comment by clicking the 'Add comment' in the right side.



| Participant Id | # | Medicine pack Id | Dispense timestamp | Dispensator | Comments | Add comment |
|----------------|---|---------------------|--------------------|-------------|--|-------------|
| DK01013 | 7 | 10040 | 08-02-2018 09:51 | majnie | 08-02-2018 09:52: dispensering gået galt | Add commen |
| DK01013 | 6 | 10036 | 08-02-2018 09:42 | majnie | 08-02-2018 09:50: kan ikke findes | Add commen |
| DK01013 | 5 | 10035 | 04-02-2018 17:25 | YOUR_NAME | | Add commen |
| DK01013 | 4 | 10034 | 04-02-2018 14:47 | My_Name | 09-02-2018 12:31: Ampule 2 and 3 were lost before administration | Add commen |
| DK01013 | 3 | 10032 | 02-02-2018 13:18 | Jens | | Add commen |
| DK01013 | 2 | 10029 | 01-02-2018 14:15 | rrtuysrtys | | Add commen |
| DK01013 | 1 | 10015 | 01-02-2018 09:30 | System | 01-02-2018 09:30: Dispensed by randomisation system | Add commen |



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Patients will be randomised to receive either

<u>Active drug:</u> haloperidol 2.5 mg (0.5 ml) x 3 daily and if necessary, additional as needed doses to maximum of 20 mg/day (total of 4 ml of haloperidol (5 mg/ml)).

OR

<u>Placebo</u>: isotonic saline (sodium chloride 0.9%) 0.5 ml x 3 daily and if necessary, additional as needed doses to a maximum of 4 ml/day.

- The trial medication is dispensed in packages enclosing 3 ampules of trial medication.
- Each ampules contains 1 ml of active drug (haloperidol 5 mg/ml) or placebo (isotonic saline).
- After the randomisation procedure, the pack identification number of the first pack will be sent to the Email-address of the person who performed the randomisation. All allocated pack identification numbers to a selected patient can be seen in the Medication Dispensing System.
- The identification numbers of the ampules have to match the identification numbers provided for the patient in the Medication Dispensing System.
- If damage to the trial medication package is suspected, do not use the trial medication.

 Allocate a new trial medication package to the patient in the Medication Dispensing System



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<u>Instructions of trial medication administration</u>

• When dispensing the standard treatment algorithm (0.5 ml active drug/placebo x 3 daily), please dispense 0.5 ml of the ampule content and administer the medication as intravenous injection only. The remaining 0.5 ml in the ampule may be disposed.

- Administration of trial medication will continue until the patient is delirium free (2
 consecutive negative delirium scores in the same day), until discharge from the ICU, death
 or until a maximum of 90 days.
- If the patient is in need of additional trial medication, as needed doses are available until a
 daily maximum of 8 doses (20 mg/4 ml) of trial medication 3 daily doses and 5 as needed
 doses.
- When dispensing as needed doses, administer 0.5 ml at a time until the patient's level of
 agitation is accommodated. You may administrate the entire content of the ampule. This
 will minimize the waste of trial medication. Dispensed trial medication shall always be
 identified with patient ID.
- When all the ampules in the trial medication package are used, please dispense new trial medication package from the Medication Dispensing System.
- Aside from trial medication, patient management will be unaffected
- Trial medication must be kept at room temperature (0-25°C)
- Trial medication should be prescribed in the patient's medication chart or ICU chart as 'AID-ICU trial medication'. This includes two prescriptions:
 - the standard treatment trial medication 0.5 ml three times daily
 - additional as needed doses 0.5 ml with a maximum of 5 additional dispenses daily (corresponding to 20 mg of haloperidol or 4 ml of isotonic saline).

Note: If for example a daily dose has not been given, that dose can be given at any time during that day and counted as 'as needed' dose.

If you discover any irregularities with an ampule, do not proceed. Call the AID-ICU hotline at +45 9357 7750

Or Email: aid-icu@cric.nu



Instructions on how to dispense and administer trial medication Agents Intervening against Delirium in the Intensive Care Unit (AID-ICU) 8 February 2018, version 1.0

Unplanned 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 ampules are damaged, the ampule identification 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,
- then dispose the ampule in the drug waste containers normally used to dispose of antipsychotics such as haloperidol,
- c. **state** the identification number(s) of disposed ampules **and sign** the Drug Disposal Form (Trial documents, Site Master File #10, cric.nu/aic-icu) for accountability reasons, and
- d. Email the signed Drug Disposal Form to aid-icu@cric.nu.

2. Disposal of the trial medication requested by sponsor

- a. If your receive a written instruction by e-mail from Sponsor requesting disposal of specified ampule identification 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 ampules in the drug waste containers normally used to dispose antipsychotics such as Haloperidol,
- c. **state** the identification number(s) of disposed ampules **and sign** the Drug Disposal Form (Trial documents, Site Master File #10, cric.nu/aic-icu) for accountability reasons, and
- d. **Email** the signed Drug Disposal Form to aid-icu@cric.nu.