



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



Modified: February 8, 2018 at 12:44 pm



Agents Intervening against Delirium in the Intensive Care Unit (AID-ICU)



Screen, randomise and enter data



Trial medication



Trial documents

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



- Log on with the shared login of your department

AID-ICU Medication Dispensing System

Log In

Username

Password

- A list of enrolled patients at your department will appear

AID-ICU Medication Dispensing System

Du er nu i fuld skærm. [Afslut fuld skærm \(F11\)](#)

Welcome to the Medication Dispensing System for AID-ICU
 You are logged in to site DK01 desc [DK01]

Choose participant on site

Participant ID	NIN	Name	Randomisation timestamp
DK01014	D1234123412	Patient name 1	01-02-2018 11:33
DK01013	D1586582458	Mona	01-02-2018 09:30
DK01012	D1212120000	90 dage -> 1 år autoudfyld?	26-01-2018 14:24
DK01011	D6678905456	prøveknud	26-01-2018 06:25
DK01009	2906941603	Patient Name	25-01-2018 13:22
DK01008	D2154878596	John	22-01-2018 15:41
DK01007	D1587682458	ghjgj	17-01-2018 13:59
DK01006	D1258965278	jens	17-01-2018 10:10
DK01005	D4444444444	peter	15-01-2018 09:57
DK01002	D0000000002	Janus 2	10-01-2018 16:09
DK01001	D0000000001	Janus	10-01-2018 16:05

Enter your name:

Participant's previously dispensed medicine packs [Click here to scroll to top](#)

Participant Id	#	Medicine pack Id	Dispense timestamp	Dispensator	Comments	Add Comment
No participant selected						

Medicine Shipping packs on site (non empty packs)

Shipping pack Id
1002
1003
1004
1005
1006
1007
1008
1009
1010
1011
1012
1013
1014



Instructions on how to dispense and administer trial medication
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8 February 2018, version 1.0

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

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DK01001	D0000000001	Janus	10-01-2018 16:05

Enter your name:



Participant's previously dispensed medicine packs [Click here to scroll to top](#)

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	<input type="button" value="Add comment"/>
DK01013	6	10036	08-02-2018 09:42	majnie	08-02-2018 09:50: kan ikke findes	<input type="button" value="Add comment"/>
DK01013	5	10035	04-02-2018 17:25	YOUR_NAME		<input type="button" value="Add comment"/>
DK01013	4	10034	04-02-2018 14:47	My_Name		<input type="button" value="Add comment"/>
DK01013	3	10032	02-02-2018 13:18	Jens		<input type="button" value="Add comment"/>
DK01013	2	10029	01-02-2018 14:15	rntuysrtys		<input type="button" value="Add comment"/>
DK01013	1	10015	01-02-2018 09:30	System	01-02-2018 09:30: Dispensed by randomisation system	<input type="button" value="Add comment"/>

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



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

Confirmation

You are about to dispense a medicine pack to trial participant

Participant ID: DK01013
NIN: D1586582458
Name: Mona

Last medicine box was dispensed on 08-02-2018 09:51
Your name: My name is (what?)

Would you like to 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's previously dispensed medicine packs [Click here to scroll to top](#)

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	<input type="button" value="Add comment"/>
DK01013	6	10036	08-02-2018 09:42	majnie	08-02-2018 09:50: kan ikke findes	<input type="button" value="Add comment"/>
DK01013	5	10035	04-02-2018 17:25	YOUR_NAME		<input type="button" value="Add comment"/>
DK01013	4	10034	04-02-2018 14:47	My_Name	09-02-2018 12:31: Ampule 2 and 3 were lost before administration	<input type="button" value="Add comment"/>
DK01013	3	10032	02-02-2018 13:18	Jens		<input type="button" value="Add comment"/>
DK01013	2	10029	01-02-2018 14:15	rntuysrtys		<input type="button" value="Add comment"/>
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Patients will be randomised to receive either

Active drug: 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

Placebo: 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



Instructions of trial medication administration

- 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**



1. Unplanned disposal of trial medication not 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,
- b. **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** you 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.