

## Place in Site Master File #13

AID-ICU newsletter – December 2018

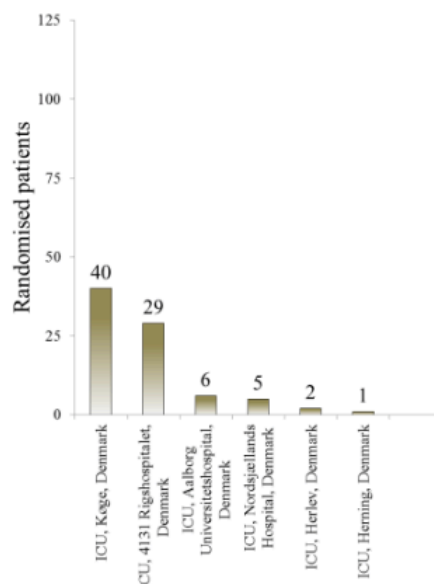
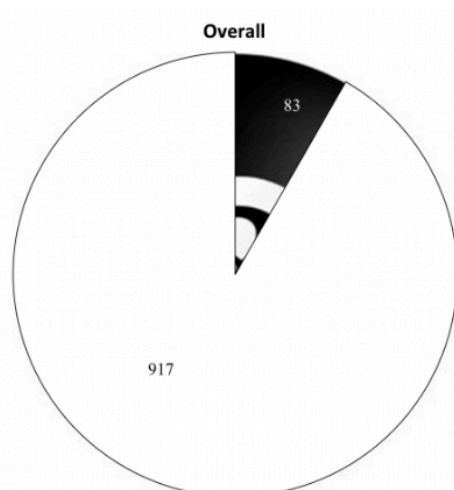
Thank you for your participation in the AID-ICU trial

**The AID-ICU team wishes you a Merry Christmas and a Happy New Year!**

### Status

Aalborg University Hospital and Region Hospital Herning have started include patients. Region Hospital Holstebro and Nykøbing Falster Hospital have also joined the trial, and are ready to start inclusion. We welcome all the new trial sites to the AID-ICU trial.

21. December 2018



### Top 3 recruiters in November

22 patients were included in the AID-ICU trial in November. The top-recruiters in this month were

1. **Rigshospitalet Dept. 4131:** 8 patients included
2. **Aalborg:** 5 patients included
3. **Hillerød:** 4 patients included and **Køge:** 4 patients included



### Welcoming new sites next month

We are looking forward to see the following sites joining us in the next month:

- Aabenraa
- Sønderborg
- Helsinki, Finland
- Turku, Finland

## A few things to highlight

### 1. Protocol version 4.1

Protocol version 4.1 is now the approved protocol of AID-ICU. Changes from 4.0 to 4.1 are minor but include a change in the coma definition.

Coma definition: Coma is defined by a RASS -4 to -5 or Ramsey sedation score 4-6, MAAS score 1-0, GCS < 8, RLS > 3. Further, RASS -3 may be considered as coma, if this is the judgment of the treating physician.

The protocol is available on the website <http://www.cric.nu/aid-icu-protocol/>. Please print and archive in your Site Master File. The previous protocol version 4.0 shall remain in the Site Master File.

### 2. Pausing and re-activating trial medication:

**Pausing of trial medication:** When a patient has two consecutive negative CAM-ICU or ICDSC (< 4) scores on the same day (morning assessment and evening assessment) the patient is classified as 'delirium-free' and the intervention is paused. Data registration and follow-up continues. We recommend pausing the trial medication on the following morning instead of after the evening assessment since patients often turn delirious during nightshift.

**Reactivation of trial medication:** If a patient turns delirious again (positive CAM-ICU or ≥ 4 ICDSC), trial medication shall be re-activated and the patient shall resume the allocated treatment.

A standard operating procedure on how this is practically done is now available on the website: SOP Trial medication <http://www.cric.nu/aid-icu-sop-trial-medication/>

## Danish Investigator meeting at Hindsgavl Symposium

You are all invited to our CRIC Investigator meeting, which will be held at **Hindsgavl Symposium on January 25<sup>th</sup> at 17.45 pm**. Here we will discuss the progress of the current CRIC trials (AID-ICU, HOT-ICU and CLASSIC). The AID-ICU team will give a brief status of the trial and there will be plenty of time to answer any questions you might have. We hope to see many of you there!



Kind Regards

Lone and Nina