Place in Site Master File #13

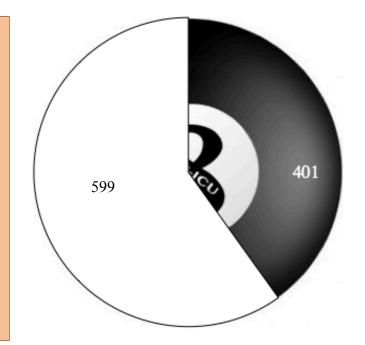
AID-ICU newsletter – November/December 2019

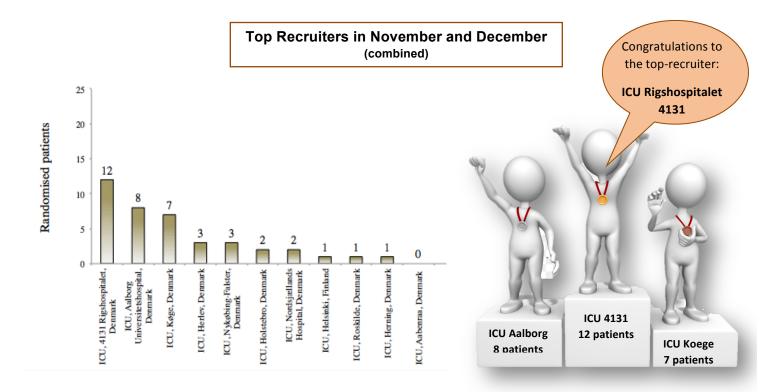
HAPPY NEW YEAR to all our colleagues in the AID-ICU trial!

STATUS

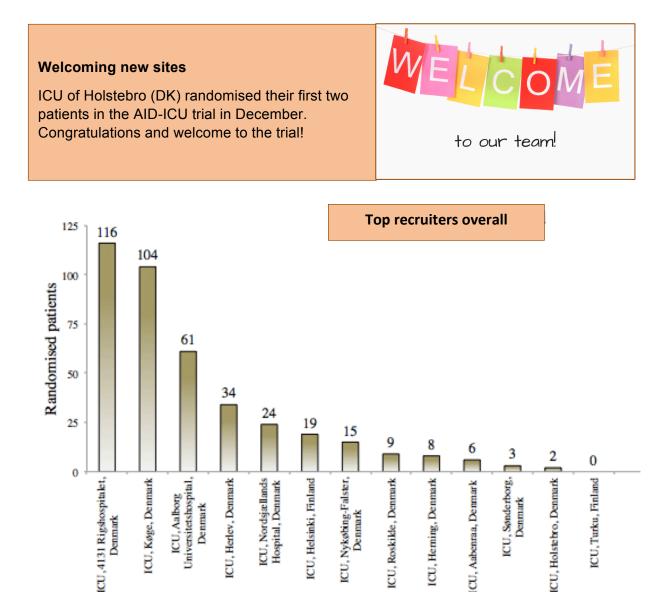
Patient no. 400 was included at Zealand University Hospital, Koege by our Primary Investigator Hans Christian Boesen – great job! We are pleased to have reached 40% of the total inclusion number and also last checkpoint before our interim at 500 patients.

We hope that 2020 will be a prosperous year where we strive to increase randomisation rates by welcoming more international trial sites. Initiation of international sites has been delayed primarily due to challenges in contracting concerning GDPR legislation. The ICU of Monza University Hospital is ready to randomise and we hope to see the first Italian randomisation soon. Further 8 Spanish sites are expected to join the trial in the first quarter of 2020.





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Important news from the coordinating centre

Denmark

- 1. Instructions on how to obtain EQ-VAS is available on the website: http://www.cric.nu/sop-obtaining-eq-5d-5l/ Please print and place in SMF section 9vi.
- 2. Remember to screen all patients with either CAM-ICU or ICDSC twice daily
- Please strive to screen all patients fulfilling inclusion criteria (acutely admitted, adult patient with a positive CAM-ICU or ICDSC \geq 4) in the AID-ICU database
- 4. Please ensure that email notifications of warnings and major protocol violations are handled to secure adherence to the protocol.
- 5. Please check the site master file log (http://www.cric.nu/aid-icu-log-for-sitemaster-file/) regularly for updates.

The After-AID trial

One-year follow-up of the AID-ICU trial has been named the After-AID trial. Our ICU nurse and subinvestigator Camilla Bekker Mortensen is in charge of the follow-up study which include 1-year mortality and health related quality of life measures (EQ-5D) from all survivors of the AID-ICU trial. At selected sites in Denmark she will also measure cognitive (RBANS) and physical function (IADL, Grib-strength) during home visits combined with qualitative studies exploring the ICU survivors' experience of quality of life after delirium. These measures are important to achieve knowledge on the long-term consequences of delirium in ICU survivors.

Instructions on how to obtain EQ-VAS is available on the website (see important news for link).



Remember the Coordinating Center is always available on the:

AID-ICU HOT-LINE: +45 93 57 77 50

www.cric.nu/aid-icu

Kind Regards from the AID-ICU team Lone (sponsor), Camilla Bekker Mortensen (After-AID) and Nina (Coordinating Investigator)

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