

AID-ICU newsletter – August/September/October 2020

Thank you for your commitment to the AID-ICU trial!

STATUS

Almost 2/3 of the total patient population has been included in the AID-ICU trial. We are picking up speed and getting back to normal after the pandemic put a halt to inclusion at many sites in the spring. The second wave of the pandemic have struck Europe hard and many countries are struggling with high incidence rates including Denmark. The health care system in Denmark is however better fit for this second wave and as opposed to the first wave all research activities are still running. We are still fighting to improve outcomes for the most vulnerable patients in the ICU – the delirious patients.

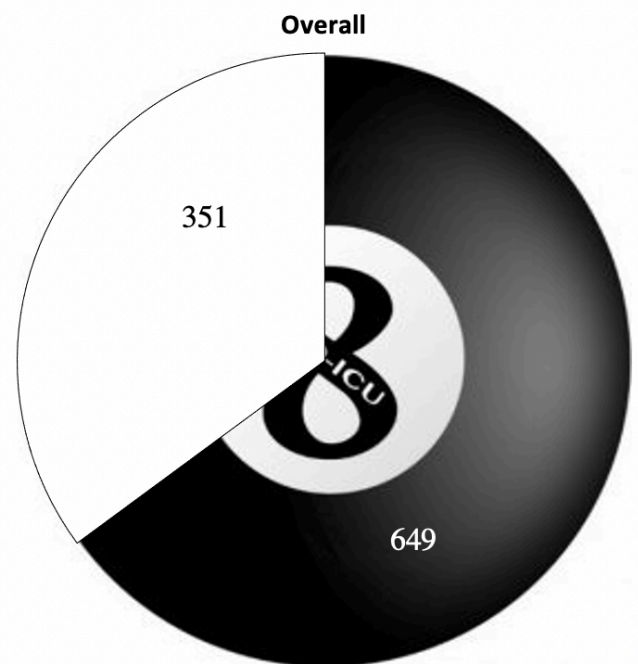
INTERIM ANALYSIS

Our Data Monitoring and Safety Committee (DMSC) held their interim meeting on the 28th of September 2020 to evaluate data from the interim analysis performed on the first 500 patients included in the AID-ICU trial. Sponsor and Coordinating Investigator presented the data on an online investigator meeting the 9th of October. If you did not have the chance to participate, we will present some of the data in this newsletter (see box below). Our DMSC consist of

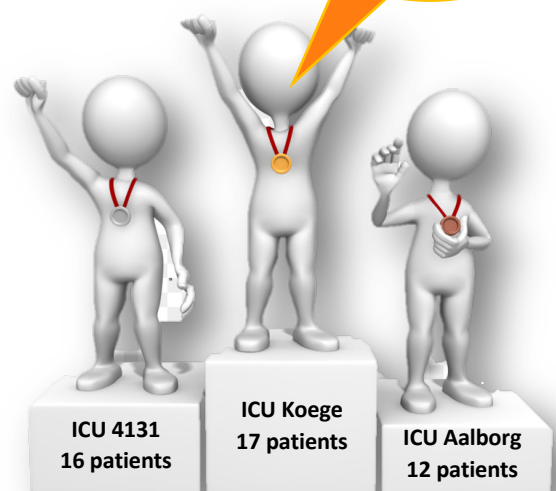
- Danny McAuley, Professor of Intensive Care Medicine, Queens University Hospital. Belfast.
- Andreas Kryger Jensen, Associate Professor, University of Copenhagen Section of Biostatistics, Denmark
- Hallie Prescott, Associate Professor, Division of Pulmonary & Critical Care Medicine, University of Michigan Health System, USA.

The DMSC recommended that the study continues as per protocol.

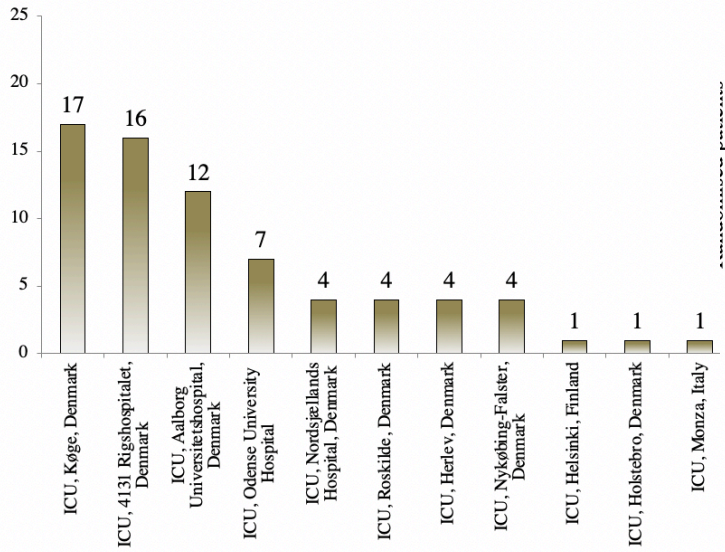
A copy of the report is attached to this newsletter.



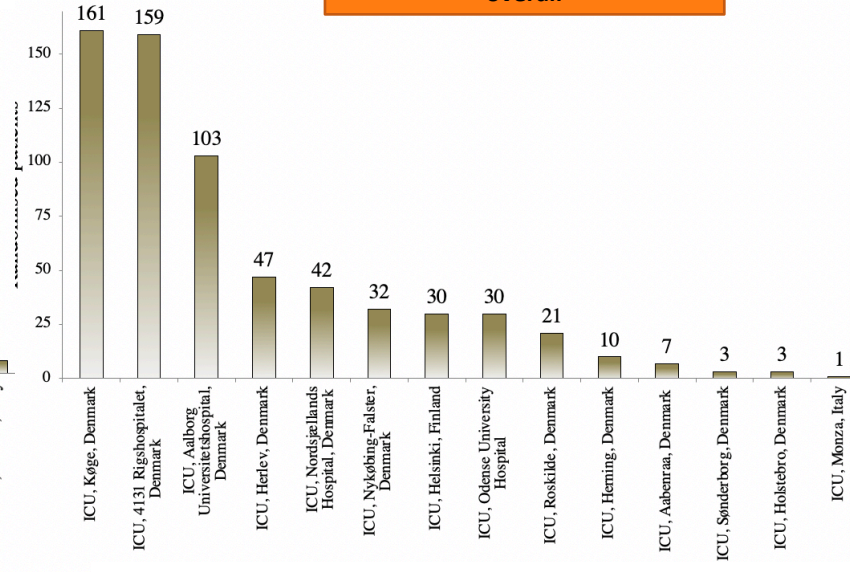
Congratulations to the top-recruiters:
ICU Koege
ICU 4131
ICU Aalborg



**Top Recruiters in
August, September and October (combined)**



**Top Recruiters
overall**



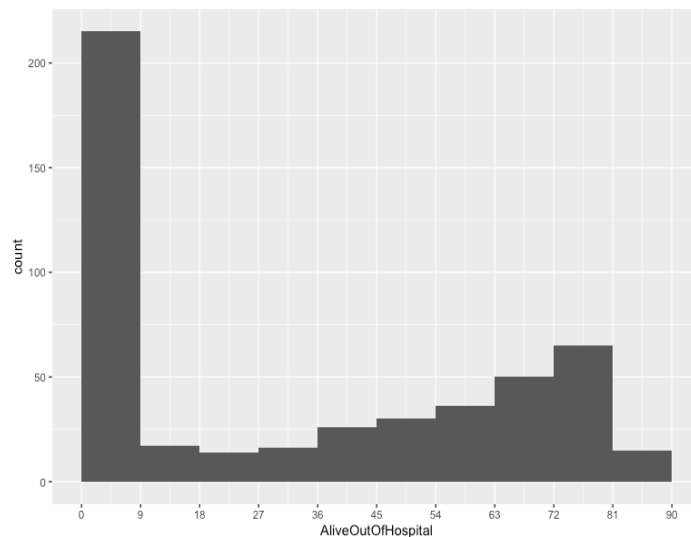
Interim data

Of the 500 included patients 196 (39%) were dead at 90day follow-up, while 295 (59%) were alive. We had missing data from 9 patients (2%). Below is our primary outcome 'Days alive and Out of Hospital' (DAOH) illustrated in a histogram. Note that 0 DAOH accounts for in-hospital mortality and patients that are still admitted to hospital at 90-day follow-up. The largest bar illustrates these patients. The median DAOH was 25, while interquartile range was 0-66.

Safety data of the 500 patients showed that 8 patients had experienced Serious Adverse Reactions (SARs). Five were Ventricular Arrhythmia (VT/VF), 1 Malignant Neuroleptic Syndrome and 2 Hepatic Failure. 286 patients have received escape during the intervention period.

Protocol Compliance

10% of the included patients had a major protocol violation registered during the intervention period. 4% due to use of open-label antipsychotics, while 6% was due to protocol deviations in management of trial medication.



Data and Safety Monitoring Committee Report

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

Date: 28.09.20

Chair: Prof Danny McAuley Professor of Intensive Care Medicine
Queen's University Belfast

DMEC Members: Andreas Kryger Jensen
University of Copenhagen
Section of Biostatistics, Denmark

Hallie Prescott
Division of Pulmonary & Critical Care Medicine
University of Michigan Health System, USA

No new conflicts of interests were noted.

The interim analysis for the first 500 patients was reviewed. No additional open report was circulated in advance of the meeting.

Minor changes to the trial protocol were noted.

It was reported there are no new data which would impact on the current study.


No additional closed minutes were taken.

The DSMB recommended that the study continue as per protocol.

Date of next meeting: No further DSMB meeting is planned however the DSMB would be agreeable to convene at the request of the study team.

DSMB Chair

Print Name: Danny McAuley



Signature: Date: 29.09.20

Important news from the coordinating centre

1. Remember to screen all patients with either CAM-ICU or ICDSC twice daily
2. Please strive to screen all patients fulfilling inclusion criteria (acutely admitted, adult patient with a positive CAM-ICU or ICDSC ≥ 4) in the AID-ICU database
3. Please check the site master file log (<http://www.cric.nu/aid-icu-log-for-site-master-file/>) regularly for updates.

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)