

Place in Site Master File #13

AID-ICU newsletter – September/October 2021

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

STATUS

Less than 100 participants to go, the finish line is within sight, and we are eager to cross it with you. We hope for your continued support and expect to finish inclusion of participants in the first quarter of 2022. Hopefully we will have results ready next summer 2022.

Important dates and deadlines

Open Clinica and Meddis (trial medication system)

Our database Open Clinica and trial medication dispensation system Meddis will be **down for maintenance on the 15th of November 2021 during daytime**. Downtime will be up to 8 hours. Please be aware that there will be no access to OpenClinica and Meddis during the maintenance. If you are in need of randomising patients or dispense trial medication please call the AID-ICU hotline +45 93 57 77 50.

Trial sites and expiry of trial medication

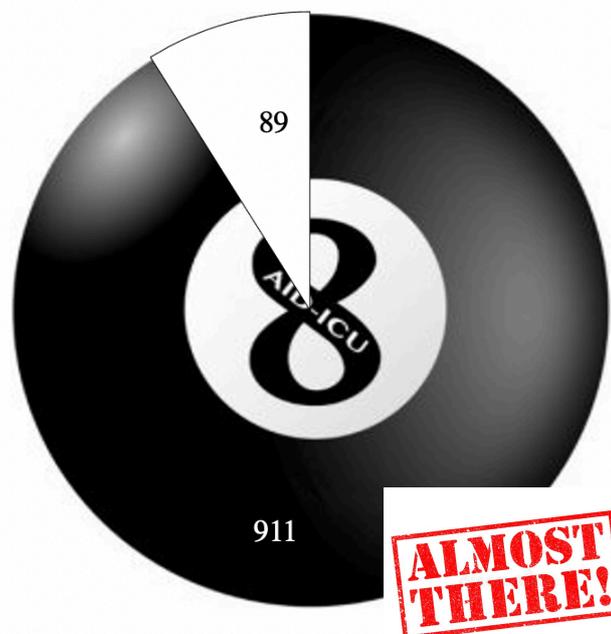
Most sites have trial medication that will expire January 1st, 2022. To minimise cost of production and distribution of trial medication, only few sites will continue recruitment in 2022. Expired trial medication shall be registered on the disposal form, which is sent to the coordinating investigator. When this is approved, trial medication may be disposed. The coordinating investigator will contact you again when this is due.

Closing visit by Monitor

The GCP unit or international monitors will perform a closing visit at each closing site at the beginning of 2022. The coordinating investigator will inform monitors which sites are closing and they will contact you for further arrangements.

Case-Money

The CRIC account is closing ultimo 2021 and consequently, we need to pay case money in advance. This information has already been sent to sites, please make sure that the CRIC office has your invoice before December 10th 2021.

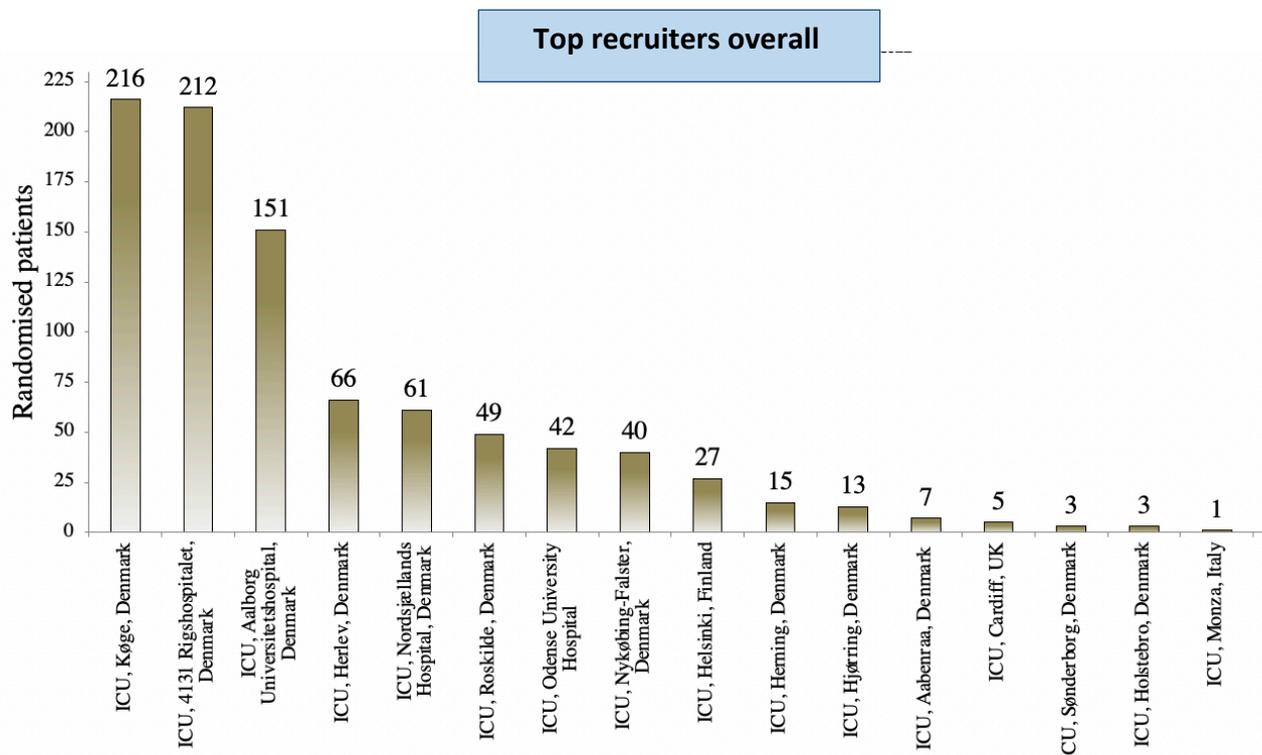


THIS PERIOD RECRUITER-CLIMBER:

**ICU Hjørring and
ICUs of Aalborg**
For keeping high inclusion for several months

A special thanks to
Kjeld Damgaard, Lillian Lundberg and their team.
Sven Weber, Inge Madsen, Line Nielsen, Anne-Marie, Rine, Anne-Sofie, Stine and their team.





Other important news from the coordinating centre

1. Co-enrolment with REVIVAL and BLINGIII is approved. <http://www.cric.nu/aid-icu-co-enrolment-list/>
2. Please strive to keep protocol compliance, we have had an unfortunate increase in protocol violations due to open-label antipsychotics. It is very important to manage delirium with trial medication followed by escape medication when trial medication is insufficient for safe delirium management. Please check SOP Trial medication (<http://www.cric.nu/aid-icu-sop-trial-medication/>).
3. Please ensure that email notifications of warnings and major protocol violations are handled to secure adherence to the protocol.
4. 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 (After-AID) and Nina (Coordinating Investigator)