

Place in Site Master File #13

AID-ICU newsletter – January/February 2021

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

STATUS

Until now, a total of **735 patients** have been recruited to the AID-ICU trial, and we are close to inclusion of **75%** of the total sample size. Our goal is to complete inclusion of patients in 2021. So far we have been able to include around 300 patients annually, so the goal should be within reach. **We therefore sincerely hope that you will be able to provide an extra support of the trial at this final stage**, and commit to recruit the last 25% of the study population within 2021. **The urgent need of finishing the trial in 2021 is emphasized by a challenge in delivery of trial medication.** This is due to expiry of trial medication at many sites and a high level of wasted trial medication. We should be able to finish the trial with the current supply of trial medication, however we need to minimise waste at sites and to recruit the remaining patients within 2021, **since all trial medication will expire at the end of 2021.**

We hope that by this time next year we will be able to deliver results of this very important trial.

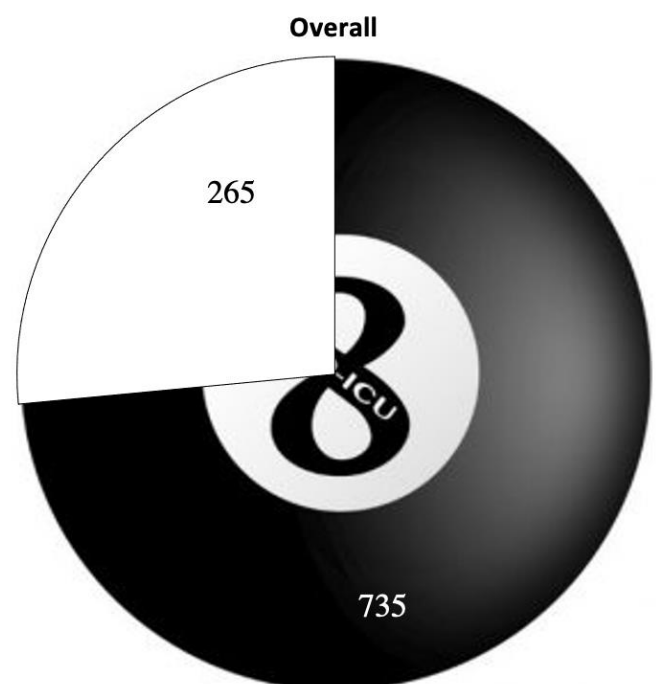
On behalf of the steering committee

Ole Mathiesen (Initiator)

Anders Perner (Initiator)

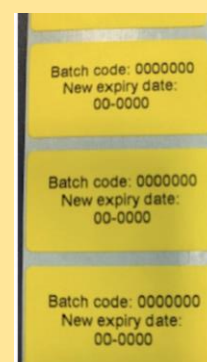
Lone M. Poulsen (sponsor)

Nina Andersen-Ranberg (Coordinating Investigator)

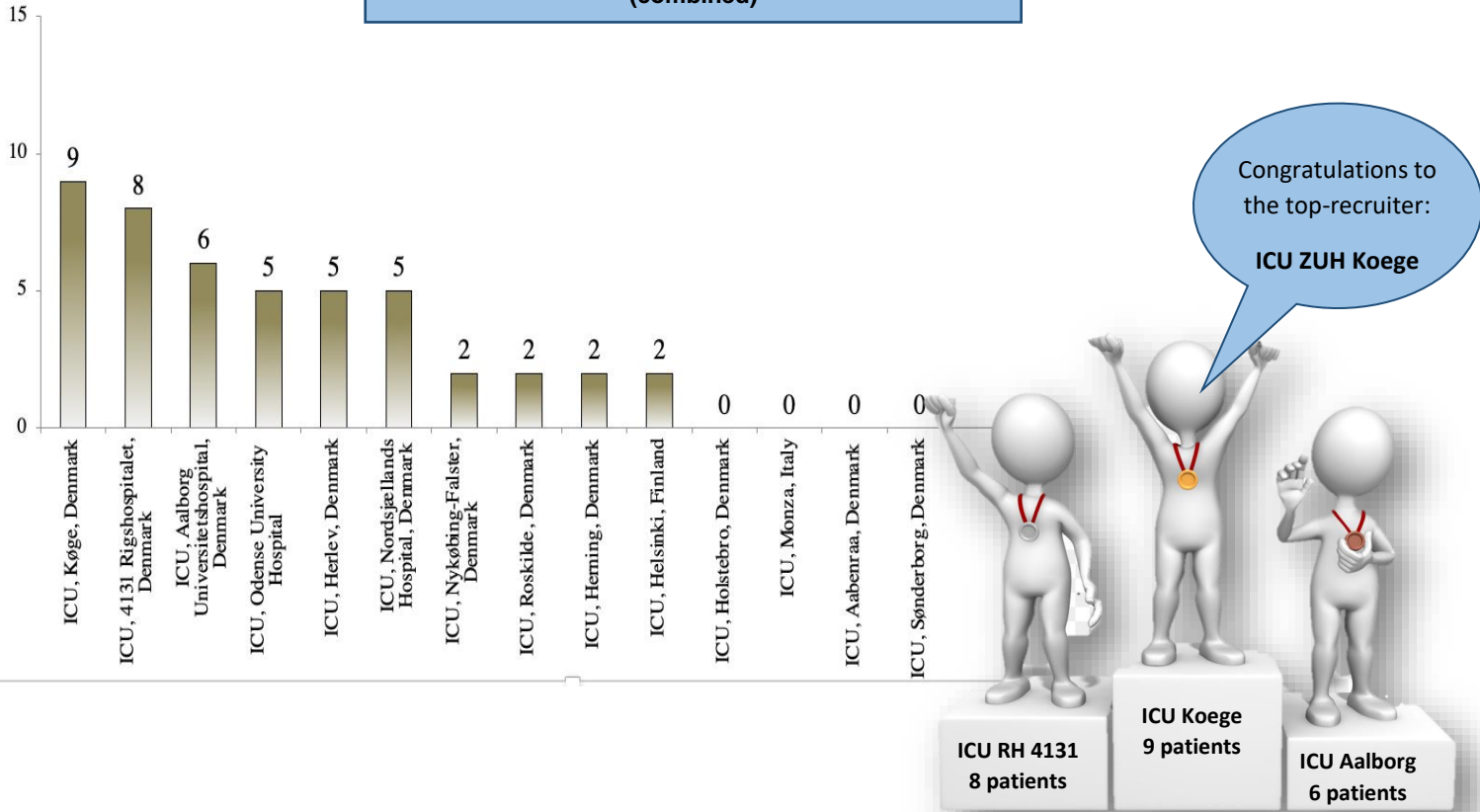


Important Notice about Trial medication

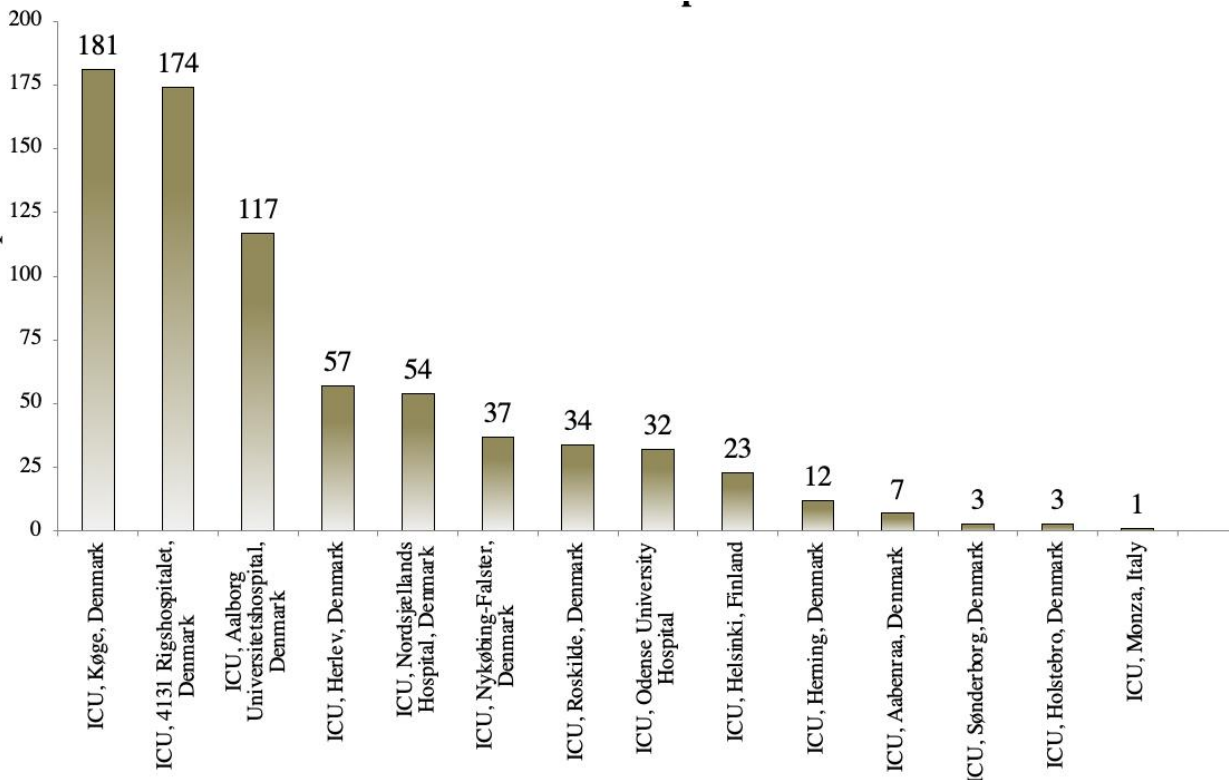
Many sites have trial medication stored that will expire at the end of April 2021. Unused trial medication with this expiry date needs to be disposed. Please fill in the drug disposal form available at the website (<http://www.cric.nu/aid-icu-drug-disposal-form/>) and place in SMF section 10. The coordinating investigator will contact sites at the end of April to make sure that expiring medication will be disposed according to national regulations.



Top Recruiters in January and February (combined)



Top recruiters overall



Other important news from the coordinating centre

1. The AID-ICU study has been approved by danish authorities to extent our inclusion period. Please insert attached extended approvals from Danish Medicines Agency and Danish ethical committee in section 4 of the SMF. For National Investigators please check national approvals for expiry.
2. Please strive to keep protocol compliance, we have had an unfortunate increase in protocol violation 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.

Welcoming to ICU Cardiff, University Hospital of Wales

National Investigator Matthew Morgan and his research team in Cardiff has been initiated in the AID-ICU trial last week. We are looking forward to welcome patients from Wales in the AID-ICU trial.

Welcome to ICU at Hospital Arnau de Vilanova de Lleida

National Investigator of Spain Jesus Caballero and his team were also initiated in the AID-ICU trial in November. We hope to see Spanish patients in the trial very soon.



to our team!

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)**