



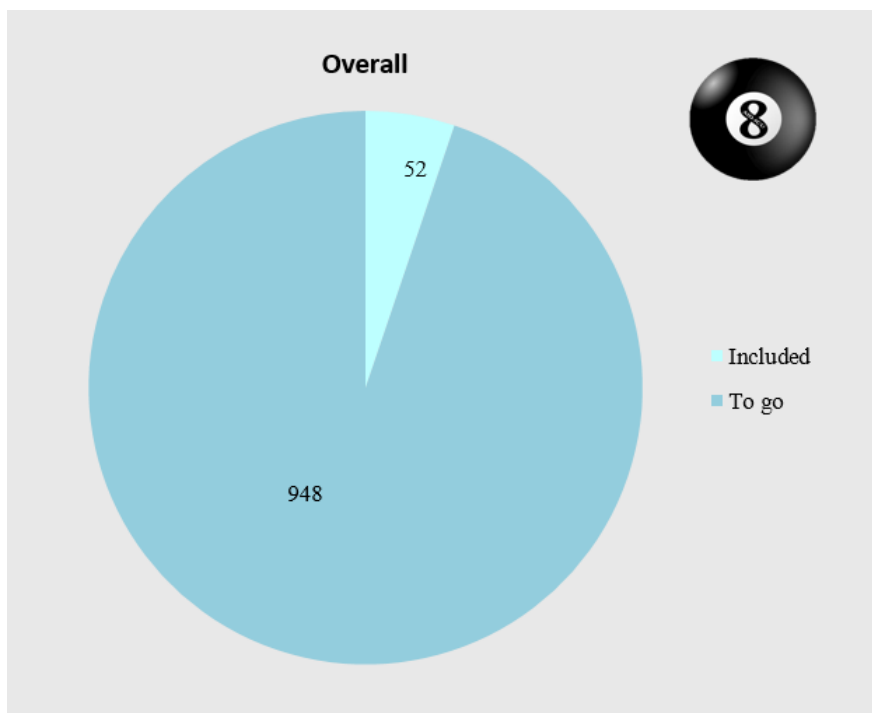
Place in Site Master File #13

AID-ICU newsletter – November 2018

Thank you very much for participating in the AID-ICU trial.

Status

The AID-ICU trial started inclusion at Zealand University Hospital, Koege June 12th, 2018. After a pilot period of 3 months, Rigshospitalet Department 4131, Zealand University Hospital Roskilde, Herlev Hospital and Hillerød Hospital joined the trial. Inclusion rate is picking up pace as more centers joins the trial – keep up the good work!



Top Recruiters in October

17 patients were included in the AID-ICU trial in October. The top-recruiter in this month was

1. Rigshospitalet Department 4131 (11 patients included)



Welcoming new sites next month:

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

- Aalborg University Hospital
- Herning Hospital
- Holstebro Hospital
- Nykøbing Falster Hospital

A few things to highlight

1. Investigators in Region H and Region S: The trial drug prescription was temporarily removed from Sundhedsplatformen due to errors in the system. The drug prescription is now replaced with two new prescriptions. The names are:
 - Projekt AID-ICU fast dosering (ID: 218880)
 - Projekt AID-ICU ved behov (ID: 218880)

They can be extracted from Nina Christine Andersen-Ranberg preference list.

2. There have been two poor metabolizers of Haloperidol among the first 50 included patients. If needed it is possible to reduce the dose to 0.25ml trial medication (corresponding 1.25mg haloperidol). This is documented in the eCRF dayform question D5g.
3. A standard operating procedure (SOP) concerning definition and data registration of Escape medications is now available on the website (<http://www.cric.nu/aid-icu-sop-escape/>)

AID-ICU at European Delirium Association 2018 in Utrecht

Lone Musaeus Poulsen (sponsor), Nina Andersen-Ranberg (coordinating investigator) and Stine Estrup participated in the annual European Delirium Association Meeting.



MIND-USA

On October 22nd the MIND-USA trial was published in NEJM, a RCT comparing the effect of Haloperidol, Ziprasidone vs. placebo on delirium duration in patients with acute respiratory failure or shock. The use of Haloperidol or Ziprasidone, as compared with placebo did not significantly alter the duration of delirium. These results are of high interest to the AID-ICU trial since the trial indicate no benefit of antipsychotics in the treatment of delirium. However, more trials are needed since MIND-USA were based on a selected study population and primarily on hypoactive delirium. The trial was not adequately powered to draw any conclusions on mortality (n= 566). Concerning safety and harm the trial showed no difference between trial groups. We are looking forward to a future updated review with results from MIND-USA, AID-ICU and possibly other trials.

Original paper: <https://www.nejm.org/doi/full/10.1056/NEJMoa1808217>

Editorial: https://www.nejm.org/doi/full/10.1056/NEJMe1813382?query=recirc_curatedRelated_article

Kind Regards Lone and Nina