

NEWSLETTER

Dear friends and colleagues,

The second domain has commenced after a reasonably smooth process at the authorities thanks to Eric, Ruben and the domain MC for a well prepared DSA and the INCEPT admin team. This shows that the platform trial promise has come through on the paperwork-side.

Also the work in many groups around new domain – 11 in total – shows that INCEPT does what it should on the clinical academic side, engaging a lot of colleagues from many sites on diverse clinical questions.

The INCEPT office and national investigators work hard with their teams to get the paperwork to get the next countries approved by the authorities. Due to CTIS constraints, this will happen in batches, at least one in October and one in December.



Updates

Methods:

The template for domain-specific appendices has been updated following approval of the first two domains. New domains should be written using the newest template - please reach out to the INCEPT coordinating center when you need the newest version of the template.

Funding:

The AFIB and HCO3 - domains have grant applications in process.

Clinical domains

Albumin domain:

57 patients have been enrolled at 5 active sites. The main reason for exclusion has been use of albumin. The next milestones will be first participant outside DK, annual safety reporting late February (1-year after approval) and feasibility phase conclusion after 200 participants being followed-up.

Thromboprophylaxis domain:

The first patient was randomised in Copenhagen in the INCEPT-Thromboprophylaxis domain on September 18.

Calcium domain:

The survey was launched in week 34 (August 18) and will run until the end of September. We are looking forward to the results with great interest. After this, we will assess the conditions for proceeding with more detailed RCT planning.

Vasopressin domain:

The survey regarding Vasopressin and Epinephrine as second-line vasopressor in septic shock patients has been closed in Denmark. International distribution during the fall is being planned.

Atrial Fibrillation domain:

This domain will involve patients with atrial fibrillation in the ICU, randomized to three different treatment arms (amiodarone, digoxin, and beta blockers). We are in the early phase and are currently working on the study synopsis.

If you are interested in joining the management committee, please contact Anna Gundlund at anna.gundlund.lorentzen@regionh.dk



Upcoming domains

We are in the early stages of planning an INCEPT domain focusing on platelet transfusion. At this stage, we would like to establish a research group of interested people.

If you would like to be involved, please contact me at jehad.ahmad.barakji@regionh.dk. A first meeting will be arranged to discuss the scope and next steps. We look forward to hearing from you.

If you have any ideas, suggestions, or updates to coming or previously discussed domains not listed above (i.e., domains that are early in the planning phase), that you would like to discuss at future meetings, please reach out to Morten (morten.hylander.moeller@regionh.dk).

With collegial regards,

Anders Granholm, Anders Perner, Morten Hylander Møller,
Benjamin Skov Kaas-Hansen, Maj-Brit Nørregaard Kjær, and Rikke Faebo Larsen

on behalf of the INCEPT Coordinating Group