GODIF Newsletter March to May 2023

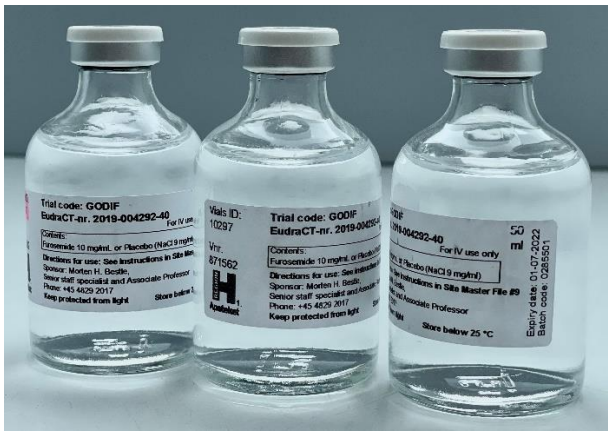
Thank you for committing to the GODIF trial!

Dear friends and colleagues,

Thanks to all for your big efforts in screening and including patients in the GODIF trial.

A big welcome to the ICU in Viborg and Randers. The GODIF trial has been approved in the Netherlands and the ICU in Groningen is expected to start including patients during the summer. We are very happy that the GODIF team now consists of 5 participating countries and 21 trial sites.

Most of the sites have trial medication which expires on 01.07.2023 or 01.09.2023. The sites that have medicine with an expiry date of 01.07.2023 will receive new medicine at the end of May or in June. All expired vials must be discarded following your normal practice for discarding medicine at your site. You will be asked to fill in a disposal form with all the expired and discarded vials. Afterwards, they will be removed from the medicine dispensing database, so only new medicine can be allocated to your patients.
Sites with medicine expiring 01.09.2023 will receive new medicine during the summer.



GODIF

A new amendment to the protocol

We are continuously expanding the GODIF network by adding new countries and sites. We have recently experienced that some countries have not been able to approve our trial drug (produced by the Capital Region Pharmacy in Denmark). The GODIF steering committee has therefore decided that new countries can participate in GODIF with the use of shelf medicine and an unblinded third party to prepare the medicine in a blinded form. This is an acceptable method which will not affect the quality of the trial.

The amendment is necessary to increase the number of active sites and the inclusion rate. We also find that more participating countries will make the results more applicable to a larger patient population.

Attention points for data entry

Monitoring reports from the sites have highlighted the following attention points.

Screening form:

Data entry at A3: Diuresis for the last 24 hours. *Please insert the urine output for the last 24 hours prior to the inclusion time*.

Day forms:

The first and the last day form will normally have a reduced span (less than 24 hours), which affects how the daily fluid balance and urine output must be registered for these day forms.

Data entry at D1: Daily fluid balance. *The fluid balance on the 1. day form must be registered for the preceding 24 hours (even the first GODIF day normally is shorter than 24 hours). The fluid balance on the last GODIF day must be calculated for the actual hours until discharge from the ICU or death.*

Data entry at D2: Urinary output on this day. *For both the first and last day form the urine output must be calculated for the actual hours the patient is included in the trial.*

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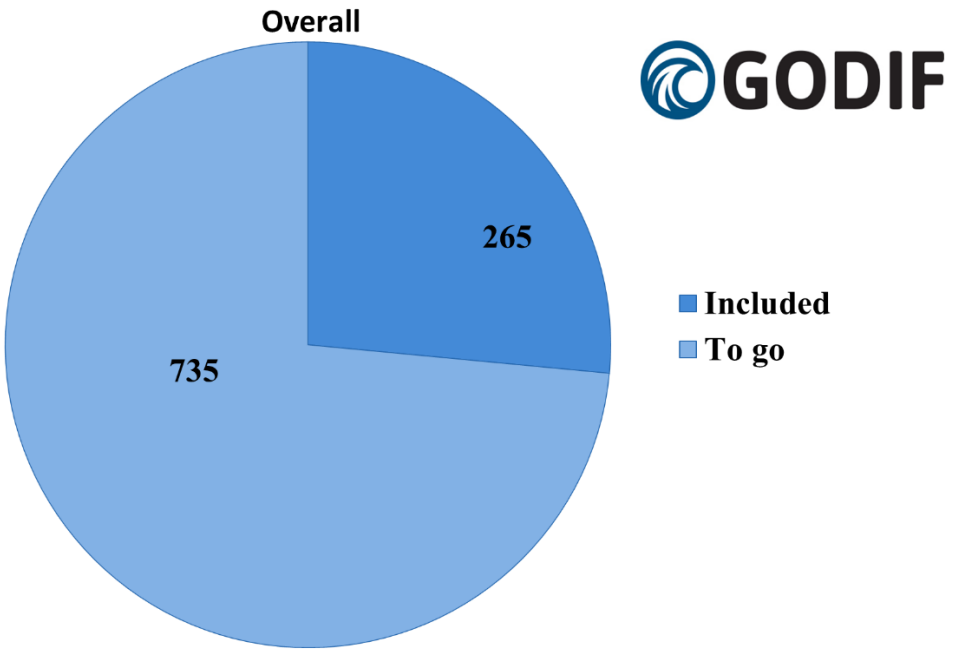
Status of the recruitment the 15.05.2023:



GODIF

New documents for your site master file.

- Forsøgspersoners rettigheder i et sundhedsvidenskabeligt forskningsprojekt (opdateret version fra d. 11.03.2023) (*Danish sites only!* Site master file section 7c)
- New amendment to the protocol version 2.7 (site master file section 1b)
- Approvals of the new amendment (site master file sections 4a and 4c)

1-year follow-up

More and more sites have started the 1-year follow-up. A MoCA certification is mandatory to do the telephone interview. It takes about 1 hour to take the course online. The MoCA cognition has now made it free for students, faculty members, academic researchers, and publicly operated healthcare institutions. But you need to apply for free access. They require proof of status. Getting the approval might take some time. Please start the process of getting certified 1-2 months before you have to start the 1-year follow-up. If you or some of your staff are already certified and ready to do the follow-up – please send a copy of the certificate to the coordinating centre. If you do not get approved for a free certification – please get in touch with the coordinating centre for assistance. Follow this link to start the process https://mocacognition.com/training-certification/

The new MoCA-mini is slightly different from the former versions. Please read the instruction before you start. The instructions can be found on the homepage https://www.cric.nu/moca-mini-test-and-instructions/

The Coordinating Center is always available on the
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Kind Regards form the GODIF team
Morten (Sponsor) and Sine (Coordinating Investigator)

All the best,

Morten and Sine