

## **GODIF Newsletter June to August 2022**

## Thank you for committing to the GODIF trial!

Dear friends and colleagues,

We hope you have had a wonderful summer. Thanks to all of you who have included patients during the holiday season.

We are happy that we can welcome Herlev ICU to the GODIF team. More sites are in the pipeline and will join in the autumn.

In June you have all received the newest protocol version 2.7 with only minor changes - funding and timeline of the trial were updated.

If a patient experiences a SAR or SAE - please send us an email explaining what happened and how you handled it and let us know if it resulted in withdrawal from the trial. Please keep these emails in your site master file as documentation. All SAR/SAEs must be followed by a mail to the coordinating centre.

Protocol violations might happen. We monitor these violations and the reasons behind to ensure protocol adherence and due to safety. Please inform us by email and explain how it was handled if you have protocol violations at your site.

We have started a document with frequently asked questions about the GODIF trial and the eCRF. It will be updated regularly and can be found on the homepage:

http://www.cric.nu/godif-frequently-asked-questions-about-the-trial-and-the-ecrf/

Let us know if you have unanswered questions that would be of general relevance, and it will be added to the document with an answer.

We are happy to inform you that our review of "Loop diuretics in adult intensive care patients with fluid overload: a systematic review of randomised clinical trials with meta-analysis and trial sequential analysis" has been published. You find it in the following link:

https://annalsofintensivecare.springeropen.com/articles/10.1186/s13613-022-01024-6

The review found very uncertain evidence for the effect of loop diuretics on mortality and serious adverse events and reactions. Larger randomised clinical trials are needed and with GODIF trial we are trying to contribute with more knowledge.



A protocol article for the GODIF trial has also been published "Goal directed fluid removal with furosemide versus placebo in intensive care patients with fluid overload: A trial protocol for a randomised, blinded trial (GODIF trial)"

https://onlinelibrary.wiley.com/doi/10.1111/aas.14121



New documents for your site master file.

An updated EudraCT document is available (only relevant for Danish sites)

New documents will always be attached to the newsletter send out four times a year.

1-year follow up is slowly starting at the sites. Please notice that we use the new MoCA-mini which is a bit different from the former versions. Instructions can be found in the site master file and on the homepage. Every site should have 1-2 persons with MoCA certification to do the 1-year follow-up. If none of the members of your research staff involved in GODIF has the MoCA certificate - please get in touch with the coordinating center when the time is near for you to start 1-year follow-up at your site.

The Coordinating Center is always available on the GODIF hotline: +45 48 29 67 73

Mail: godif@cric.nu

www.cric.nu/godif/

Kind Regards form the GODIF team

Morten (Sponsor) and Sine (Coordinating Investigator)

All the best,

Morten and Sine



