GODIF Newsletter June 2024 to August 2024

Thank you for committing to the GODIF trial!

Dear friends and colleagues,

We hope you all have had a wonderful summer.
We have now enrolled 556 participants – well done! In July the ICU in Bern, Switzerland, and the ICU in Herlev, Denmark were the top recruiters. Congratulations!

GODIF

Second interim analysis

In August, the first 500 participants will complete their 90-day follow-up, allowing us to proceed with the second interim analysis. This analysis will focus on our primary outcome – days alive and out of hospital at day 90 - as well as the safety measure – the number of patients with one or more serious adverse events or reactions by day 90. An independent international data monitoring committee will review the blinded data, and we expect their recommendations on the trial's future conduct in early September.

Trial progress and challenges

Despite an increasing number of participating sites, the recruitment rate for the GODIF trial has been slower than anticipated. As a result, we have extended the trial's duration, with the goal of completing enrolment by early 2026. This extension has led to a significant rise in costs, particularly in the production and distribution of trial drugs, which have doubled. Consequently, we have had to make difficult decisions to optimize our resources. We will be closing sites that have been inactive for over a year or have had only minimal enrolment. This includes sites in Norway, Iceland, and Finland, as well as Aarhus and Vejle in Denmark. Currently, the trial remains active in Denmark, the Netherlands, and Switzerland, with 16 active trial sites.

Looking ahead, we are pleased to announce that Sweden is expected to join the trial this autumn, with Södersjukhuset in Stockholm as the participating site. Additionally, we anticipate welcoming three new trial sites in Australia later this year. We are hopeful that these new sites will help increase our enrolment rate.

Regulatory compliance in the European Union

clinical trials in the European Union that are not completed by January 30, 2025, must be transferred to the Clinical Trials Information System (CTIS) under the European Medicines Agency (EMA). We have submitted the application to transfer the GODIF trial to CTIS, and it is currently under review. Once the trial is transferred and approved by the participating countries, the protocol will be updated to comply with European clinical trial legislation. This will result in changes to the consent procedures at Danish sites, and possibly also in Sweden and the Netherlands. We will provide further information on this as it becomes relevant.

Reporting of serious adverse events and reactions

Until now all centres besides Switzerland have reported the serious adverse events and reactions by email or note to file to the coordination centre. To streamline the reporting process, we have

developed a new reporting template which must be used by all centres for future reporting, except for Switzerland, which is exempt from using this form.

Thank you for your continued commitment to the GODIF trial. We appreciate your efforts and dedication as we work together to achieve our goals.

New documents for your site master file.

- Template to report serious adverse events or reactions.

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

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