



# GODIF Newsletter September to November 2023

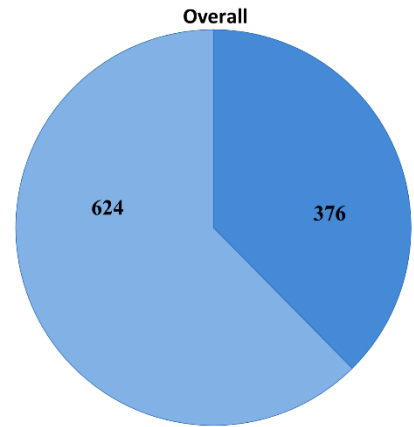
## Thank you for committing to the GODIF trial!

Dear friends and colleagues,

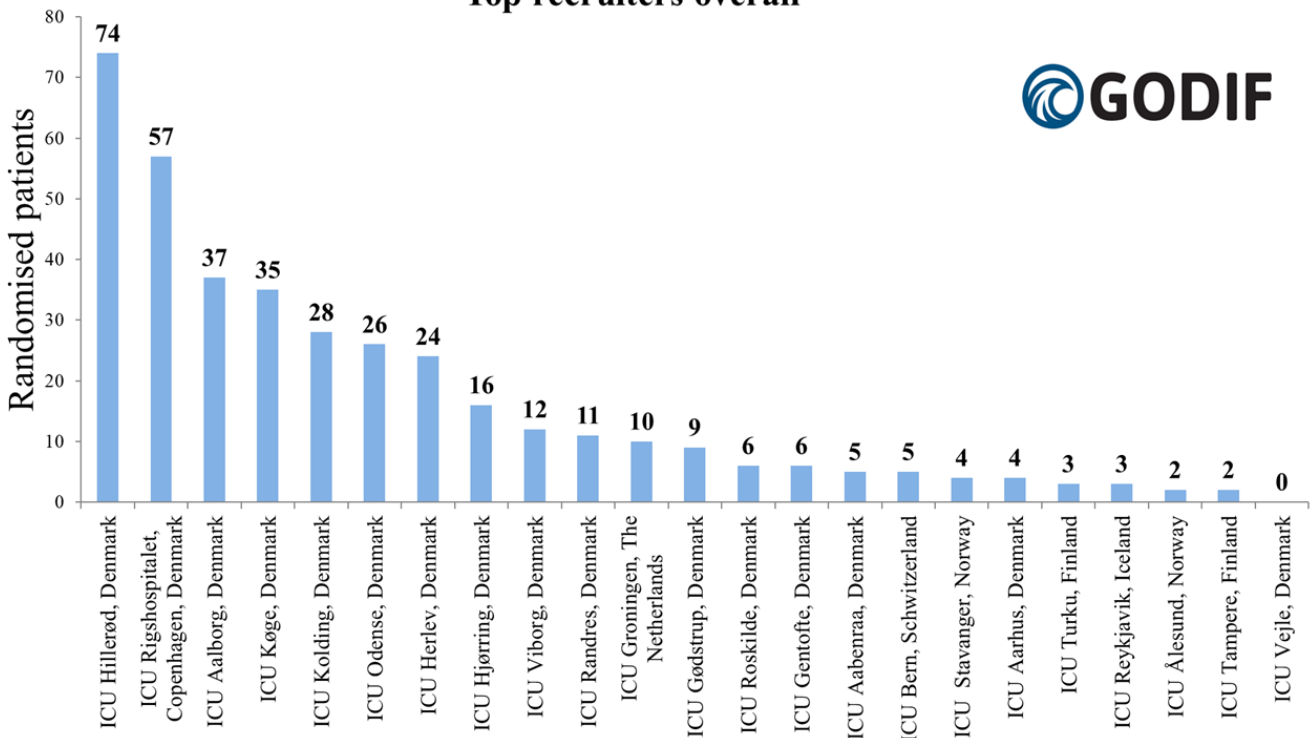
Thank you for your collaboration and work with the GODIF trial. It is highly appreciated.

A warm welcome to the University Medical Center in Groningen, the Netherlands and Inselspital University Hospital Bern, Switzerland to the GODIF team. We are now 23 active GODIF sites in 6 countries.

On the 20<sup>th</sup> of November, 376 participants were enrolled.



### Top recruiters overall



## SAP for the GODIF trial has been published

We are happy to inform you that our statistical analysis plan has now been published.

***Furosemide versus placebo for fluid overload in intensive care patients - The randomised GODIF trial second version: Statistical analysis plan.*** Wichmann S, Lange T, Perner A, Gluud C, Itenov TS, Berthelsen RE, Nebrich L, Wiis J, Brøchner AC, Nielsen LG, Behzadi MT, Damgaard K, Andreasen AS, Strand K, Jarvisalo M, Strøm T, Eschen CT, Vang ML, Hildebrandt T, Andersen FH, Sigurdsson MI, Thomar KM, Thygesen SK, Troelsen TT, Uusalo P, Jalkanen V, Illum D, Sjølling C, Keus F, Pfortmueller CA, Wahlin RR, Ostermann M, Aneman A, Bestle MH. *Acta Anaesthesiol Scand.* 2023 Sep 11. doi: 10.1111/aas.14320.

## Protocol violations

When you experience a protocol violation, kindly email, or send a note to file to the coordinating centre explaining the incident and outlining preventive measures to avoid it from happening again. These emails/notes to file must be kept in your site master file as documentation.

## Assessing fluid overload

Assessing fluid status can pose challenges as surrogate measures such as cumulative fluid balance, changes in body weight, and clinical examinations might not always show the same picture. None of these surrogate measures provide a precise assessment contributing to the complexity of fluid status evaluation. Several studies



indicate a poor correlation between changes in body weight and cumulative fluid balance.

Numerous factors contribute to this discrepancy, including the daily loss of approximately 2% of muscle mass in critically ill patients in the ICU. In cases where patients maintain a neutral fluid status during their ICU stay, weight loss is anticipated. This is important to remember when using the body weight in fluid assessment. The imprecision of all the existing surrogate measures underscores the importance of conducting assessments based on all the available data at your disposal.

**New documents for your site master file.**

- Updated EudraCT for the Danish sites
- Updated Co-enrolment list

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

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

Mail: [godif@cric.nu](mailto:godif@cric.nu)

[www.cric.nu/godif/](http://www.cric.nu/godif/)

Kind Regards from the GODIF team

Morten (Sponsor) and Sine (Coordinating Investigator)

**All the best,**

**Morten and Sine**

