



Dear all STEPCARE investigators,

Currently we have included more than 600 participants in STEPCARE which is almost 1/5 of the total trial sample size! This has been achieved in less than a year with an increasing number of sites active. Last European Autumn we had only a few sites open, but today 36 sites are activated and either recruiting or close to starting. Great job by everyone.

The focus for the next six months is to increase the number of sites to what we had in the TTM2 and TAME Trials with a total of 60-70 sites onboard. Another milestone we have passed is the trigger for the first interim analysis. Therefore, we will ask all sites to update the eCRFs for all participants that have been more than 30 days in the trial (randomized up until 15 August 2024). All data points up to the 15th of September 2024 are required to prepare the data files for the Data Safety Monitoring Committee.

DATA POINTS THAT NEED TO BE COMPLETED IN THE eCRF FOR INTERIM ANALYSIS

- Randomization form
- Background form
- Hourly data forms
- Complications form
- Discharge form
- Vital Status form -Day 30

TOP RECRUITING SITES

- Meilahti Hospital, FI (58)
- University Hospital Zurich, CH (44)
- Liverpool Hospital, AU (35)
- Sahlgrenska University Hospital, SE (35)
- Luxembourg Hospital, LU (34)
- Lubeck University Hospital, DE (33)
- St Gallen Hospital, CH (26)
- Wellington Hospital, NZ (26)
- Princess Alexandra Hospital, AU (25)
- Tampere University Hospital, FI (23)

WELCOME NEW SITES

- St Bartholomew's Hospital, UK
- Bristol Royal Infirmary, UK
- Ghent University Hospital, BE
- St George Hospital, Sydney, AU

CRF UPDATE

We recognize that the database has had many teething problems, we continue to work with Spinnaker to iron out all the current issues. Thank you for your patience, we are slowly getting there.

There will be more changes in the eCRF over the next couple of months. In particular the 6 month follow-up forms will be available, ROSC field will be editable, many of the data range fields will be amended, logic checks will be added, extra field for no available temperature and consent form – ethics date.

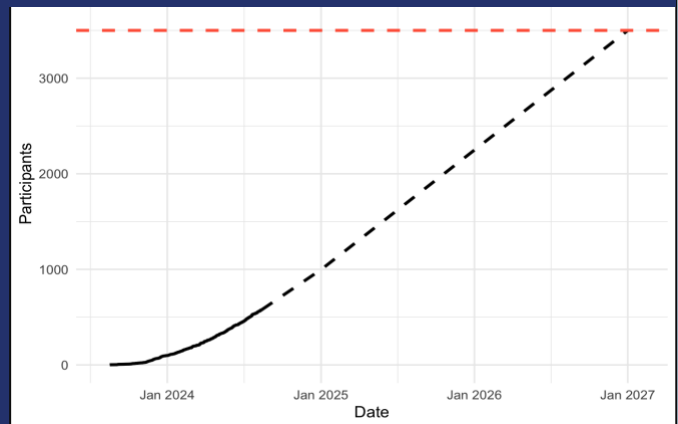


Investigator Meeting May 2024

Thanks everyone for the great investigator meeting we had in Helsingborg in May. It was very productive from both an academic and a social perspective. It has inspired us to continue with STEPCARE even in periods of too many administrative obstacles. Please see the photo attached. We hope to invite everyone to a meeting in Helsinki in June 2025 (tentative dates of Monday June 16th to Tuesday June 17th 2025).

Recruitment

Some sites continue to excel in screening and including participants. Some sites have infrastructure to recruit more participants, but we are also so grateful for smaller sites including all patients fulfilling eligibility criteria. This is the key to a successful trial. Please see the recruitment graph, with a very conservative and modest estimate. Likely, we will recruit much faster, finishing earlier during 2026.



SUB- STUDIES

There are numerous sub-studies in progress. More information on sub-studies can be found on the STEPCARE website, under the 'Substudies' heading. If interested in conducting a sub-study, please download the sub-study proposal form, follow the instructions and submit your proposal. This will be reviewed by the international sub-study committee re. approval.

FREQUENTLY ASKED QUESTIONS (FAQ)

There are many important questions that come from sites and these are always welcome. We have put together a list of frequently asked questions and answers and these can be found on the STEPCARE website under the 'FAQ' heading. Please visit the website as there are many useful documents and resources available; <https://stepcare.org>

PROTOCOL MANUSCRIPTS

The international Management Committee will circulate four protocol papers for the STEPCARE trial in the very near future. One protocol paper for each intervention and a common statistical analysis plan. We aim to submit all papers to the journal Acta Anaesthesiologica Scandinavica within the month of September 2024.

We would like to take the opportunity to thank all of the sites for their hard work and dedication towards STEPCARE. Keep up the amazing work!