Minutes from the substudy meetings on 10 and 24 September 2025

General information about substudies

- The randomization in the STEPCARE trial is progressing very well, and we anticipate completing recruitment by May 2026.
- The trial management group (TMG) encourages the conduct of substudies. However, investigators must ensure that they have obtained the necessary approvals for each substudy. Substudy principal investigators (PIs) should actively participate in the recruitment of new sites for each substudy. Additionally, participating sites must obtain ethical approval for each substudy.
- Most of the substudy eCRFs are nearing completion, and several are anticipated to be released soon.
- If a substudy protocol is to be published, it must be submitted to the TMG in advance. Publication of the substudy protocols can be in a journal or on the STEPCARE website.
- The three main papers of the STEPCARE trial will be published first. Subsequently, we will proceed with the substudies. All substudy papers must be sent to the TMG before submission.
- We will aim to be fair with authorships.
- It's crucial that participating sites in a substudy strive to include all patients in the respective substudy, potentially within a shorter timeframe. The PI of the substudy should inform participating sites about this before they join. This approach is crucial to minimize the risk of missing data. Selecting only certain patients will render the results of the substudies useless.
- For substudies that focus on a cohort with observational data, the PI should consider how the cohort is treated (e.g., as a single sample or separated samples that will be pooled).
- Only additional data points (not already included in the eCRF) can be added to the substudy eCRFs. Once the data collection for the main trial is complete, the data will be "cleaned" centrally. Subsequently, the substudy PIs can request a dataset containing the prespecified main data points merged with the additional data points.

Substudies presented on September 10, 2025

From 11:40 to 31:34:

Patrick Druwé from Belgium presenting

VICAP-CPR (Validity of ICU Clinician's Appraisal of Proportionality in CPR)

The main objectives: To what extent is the perception of (in)appropriateness of CPR by ICU doctors and ICU nurses associated with (1) their clinical appraisal of the frailty, the quality of life and the presence of severe comorbidities of the STEPCARE patient, (2) the characteristics of the ICU clinician, and (3) the cardiac arrest characteristics (witnessed arrest, bystander CPR, initial rhythm).

Please see further information at: https://stepcare.org/substudies/substudy/vicap-cpr-validity-icu-clinicians-appraisal-proportionality-cpr

From 31:35 to 52:54:

Jonatan Oras from Sweden presenting

Echocardiography substudy, The Effect of High Versus Low Mean Arterial Pressure on Left Ventricular Dysfunction in Post Cardiac Arrest Patients

The main objective: A higher mean arterial pressure will improve cardiac function, and decrease troponin release, by increasing coronary perfusion and oxygen delivery to cardiac tissue in comatose patients after cardiac arrest.

Please see further information at: https://stepcare.org/substudies/substudy/echocardiography-substudy-effect-high-versus-low-mean-arterial-pressure-left

From 52:55 to 1:04:34:

Pedro D. Wendel Garcia from Switzerland presenting

Shock-Care – focusing STEPCARE on post-resuscitation shock

The main objective: Arriving at a viable, clinically implementable and potentially therapy defining definition for post-resuscitation shock by combining a data-driven and Delphi process.

Please see further information at: https://stepcare.org/substudies/substudy/consensus-definition-post-resuscitation-shock-pre-planned-randomized-data

From 1:04:35 to 1:13:55:

Daniel Rob from the Czech Republic presenting

1. Early vs. delayed coronary angiography and PCI after cardiac arrest

2. Prediction of culprit lesion based on baseline and resuscitation characteristics in patients without stemi undergoing coronary angiography

3. Short-term mechanical circulatory support after cardiac arrest: observational analysis of IABP, ECMO, and Impella in the STEPCARE trial population

The main objectives:
1. In patients with cardiac arrest due to ACS, early coronary angiography (≤120 minutes from ROSC) is associated with improved 180-day survival compared to delayed or no angiography.
2. To identify baseline and resuscitation variables independently associated with the presence of a culprit lesion in patients without ST-elevation undergoing coronary angiography (CAG) after out-of-hospital cardiac arrest (OHCA).
3. The use of short-term mechanical circulatory support (MCS) after cardiac arrest is associated with improved 180-day survival and favorable neurological outcomes in a selected subgroup of patients with cardiac arrest. The benefit of MCS differs by device type (IABP, ECMO, Impella), initial rhythm, timing of use.

Please see further information at:

1. https://stepcare.org/substudies/substudy/early-vs-delayed-coronary-angiography-and-pci-after-cardiac-arrest
2. https://stepcare.org/substudies/substudy/prediction-culprit-lesion-based-baseline-and-resuscitation-characteristics
3. https://stepcare.org/substudies/substudy/short-term-mechanical-circulatory-support-after-cardiac-arrest-observational

Substudies presented on September 24, 2025

From 16:45 to 31:50:

Eno-Martin Lotman from Estonia presenting

> Does the use of Intensive Care Information System (ICIS) compared to paper-based charting improve time in target range (TTR) for post-resuscitation care in the intensive care units?

The main objectives: 1) Characterize the use of ICIS in a representative sample of intensive care units and 2) look into the correlations between reaching clinical treatment targets and the use of ICIS.

Please see further information at: https://stepcare.org/substudies/substudy/does-use-intensive-care-information-system-icis-compared-paper-based-charting

From 32:10 to 43:13:

Peter McGuigan from the United Kingdom presenting

1. Cerebral oximetry following OHCA
2. Transcranial cerebral doppler following OHCA
3. Optic nerve sheath diameter following OHCA
4. Pupillometry substudy
5. AMI and shock substudy
6. Circadian rhythm substudy

The main objectives for substudy 1 to 4:

- Continuous sedation vs. minimal sedation, fever control with a device vs. without a device, and MAP > 85 mmHg vs. MAP > 65 mmHg results in higher rScO2, lower Pulsatility Index, lower ONSD, lower non-invasive estimated ICP, and higher q-PLR at 72 hours.
- There is an association between low rSCO2, raised Pulsatility Index, raised ONSD, raised non-invasive estimates of ICP and low q-PLR at 72 hours and mortality and poor neurological outcome following OHCA.

Please see further information at:
1. https://stepcare.org/substudies/substudy/cerebral-oximetry-following-ohca
2. https://stepcare.org/substudies/substudy/transcranial-cerebral-doppler-following-ohca
3. https://stepcare.org/substudies/substudy/optic-nerve-sheath-diameter-following-ohca
4. https://stepcare.org/substudies/substudy/pupillometry-substudy

5. https://stepcare.org/substudies/substudy/ami-and-shock-substudy
6. https://stepcare.org/substudies/substudy/impact-time-ohca-mortality-and-neurological-outcome

From 43:20 to 57:23:

Johanna Hästbacka from Finland presenting

1. Ionized hypocalcaemia during post out-of-hospital cardiac arrest (OHCA) treatment in the intensive care units: incidence and management practices.
2. SoCARE study. Is the post-resuscitation trend in sodium levels associated with outcome? A substudy of the STEPCARE trial
3. End-of-life practices in OHCA patients with poor neurological functional outcome.

The main objectives:

1. 1) What is the incidence of ionized hypocalcaemia among OHCA patients during the post-OHCA treatment? 2) How often and in what kind of situations parenteral calcium supplementation is administered?
2. 1) Deranged sodium balance with an increasing trend in serum sodium within the first 48 hours in the ICU may associate with unfavourable functional outcomes in OCHA patients. 2) The association is different depending on the severity of disease and that in the MIRACLE2 score medium-risk group, increasing sodium levels during the first 48 hours may be associated with a favourable functional outcome.
3. What end-of-life measures are taken in participating centres when OHCA patients have an unfavourable outcome confirmed?

These three substudies are not yet approved and are therefore not published on the STEPCARE website.

From 58:00 to 1:08:56:

Joachim Düring from Sweden presenting

The PAINCARE substudy

The main objective: Patients experience pain in the ICU after cardiac arrest, which can be described and explored in terms burden to pain exposure during the first 7 days of ICU stay.

Please see further information at: https://stepcare.org/substudies/substudy/pain-after-cardiac-arrest-and-resuscitation-paincare-substudy