Plan Overview

A Data Management Plan created using DMPTuuli

Title: Sedation, temperature and pressure after cardiac arrest and resuscitation - STEP CARE

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Project abstract:

After successful resuscitation, patients who survive a cardiac arrest often remain severely ill and require intensive care. Controlling depth of sedation, body temperature and mean arterial pressure are potential treatments that may prevent brain damage. The STEPCARE trial aims to study how to best apply these interventions.

The STEPCARE trial is an international, investigator-initiated, randomized trial on three different aspects of standard care after out-of-hospital cardiac arrest. In a 2x2x2 factorial design we will compare the effect of continuous sedation vs. minimal sedation, fever management with a device vs. without a device and a higher blood pressure target vs. a lower blood pressure target.

The primary outcome of the trial will be survival at 180 days with secondary outcomes including neurological function and health-related quality of life.

Starting in 2023 the trial will include 3500 participants in Europe, Australia, New Zealand and Asia.

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Sedation, temperature and pressure after cardiac arrest and resuscitation - STEP CARE

1. General description of data

1.1 What kinds of data is your research based on? What data will be collected, produced or reused? What file formats will the data be in? Additionally, give a rough estimate of the size of the data produced/collected.

The STEP CARE study is a clinical randomized controlled trials conducted in patients. All data is collected with electronic care report forms. The full sample size is 3500 patients worldwide. The collected data are related to the management of the patient in the intensive care unit after cardiac arrest. The set of data to be collected can be found in the protocol and on the STEP CARE website www.stepcare.org : https://stepcare.org/crf

All data are collected with consent of the next of kin and/or patient. All collected is pseudoanomyzed. The eCRF is managed by a GDPR certified company and stored at a server In Stockholm, Sweden. https://spiral.co.nz/stepcare-studyplan

1.2 How will the consistency and quality of data be controlled?

We have a predefined monitoring plan n place for all sites: https://stepcare.org/investigator-site-file

We also have a data safety monitoring board that have reviewed the study results after 500 and 1250 patients. https://stepcare.org/interim-analysis

The report of the last DSMB meeting will be reviewed on August 13th 2025.

2. Ethical and legal compliance

2.1 What legal issues are related to your data management? (For example, GDPR and other legislation affecting data processing.)

The study has been approved at all sites, please see the full list and and copies of all ethical approvals:https://stepcare.org/ethics

All sites have signed data transfer agreements regarding the transfer of data to the eCRF.

2.2 How will you manage the rights of the data you use, produce and share?

This is a clinical study. We have author policies but apart from that the study´s management committee will decide on use of data. We have published study protocols outlining the analysis: https://stepcare.org/protocol

3. Documentation and metadata

3. How will you document your data in order to make the data findable, accessible, interoperable and re-usable for you and others? What kind of metadata standards, README files or other documentation will you use to help others to understand and use your data?

The data will be retained by the investigators. The ethical approvals do not make it possible make patient data public.

4. Storage and backup during the research project

4.1 Where will your data be stored, and how will the data be backed up?

All data is stored by a GDPR certified company at servers in Stockholm, Sweden
https://spiral.co.nz/stepcare-studyplan

4.2 Who will be responsible for controlling access to your data, and how will secured access be controlled?

After the completion of the trial the database will undergo cleaning in order to check for irregularities. After that the database will be locked and the analysis will begin.

5. Opening, publishing and archiving the data after the research project

5.1 What part of the data can be made openly available or published? Where and when will the data, or its metadata, be made available?

We will publish the STEP CARE trial as three separate publications in peer reviewed medical journals as we have specified in the three protocols. The analysis will be according to the statistical analysis plan:
Niemelä VH, Reinikainen M, Nielsen N, Bass F, Young P, Lilja G, Dankiewicz J, Hammond N, Hästbacka J, Levin H, Moseby-Knappe M, Saxena M, Tiainen M, Ceric A, Holgersson J, Kamp CB, Tirkkonen J, Oksanen T, Kaakinen T, Bendel S, Düring J, Lybeck A, Johnsson J, Unden J, Lundin A, Kåhlin J, Grip J, Lotman E, Romundstad L, Seidel P, Stammet P, Graf T, Mengel A, Leithner C, Nee J, Druwé P, Ameloot K, Wise MP, McGuigan PJ, White J, Govier M, Maccaroni M, Ostermann M, Hopkins P, Proudfoot A, Handslip R, Pogson D, Jackson P, Nichol A, Haenggi M, Hilty MP, Iten M, Schrag C, Nafi M, Joannidis M, Robba C, Pellis T, Belohlavek J, Rob D, Arabi Y, Buabbas S, Yew Woon C, Aneman A, Stewart A, Arnott C, Ramanan M, Panwar R, Delaney A, Reade M, Venkatesh B, Navarra L, Crichton B, Knight D, Williams A, Friberg H, Cronberg T, Jakobsen JC, Skrifvars MB. Higher versus lower mean arterial blood pressure after cardiac arrest and resuscitation (MAP-CARE): A protocol for a randomized clinical trial. Acta Anaesthesiol Scand. 2025 Jul;69(6):e70040. doi: 10.1111/aas.70040. PMID: 40392139; PMCID: PMC12090973. Copy Holgersson J, Niemelä V, Skrifvars MB, Kamp-Jorgensen C, Saxena M, Young P, Bass F, Dankiewicz J, Hammond N, Hästbacka J, Levin H, Lilja G, Moseby-Knappe M, Tiainen M, Reinikainen M, Ceric A, Düring J, Lybeck A, Rodriguez-Santos D, Johnsson J, Unden J, Lundin A, Kåhlin J, Grip J, Rosell J, Lotman EM, Navarra L, Crichton B, Knight D, Williams A, Romundstad L, Seidel P, Stammet P, Graf T, Mengel A, Leithner C, Nee J, Druwé P, Ameloot K, Wise M, Riddel J, Ahmed M, Buckel M, Mc Guigan P, Maharaj R, Wyncoll D, Thomas M, White J, Keeble TR, Pogson D, Nichol A, Haenggi M, Hilty MP, Iten M, Schrag C, Nafi M, Joannidis M, Robba C, Pellis T, Belohlavek J, Smid O, Rob D, Arabi Y, Buabbas S, Yew Woon C, Aneman A, Stewart A, Bernard S, Palmer-Simpson C, Simpson N, Ramanan M, Reade M, Delaney A, Venkatesh B, Tirkkonen J, Oksanen T, Kaakinen T, Bendel S, Friberg H, Cronberg T, Jakobsen J, Nielsen N. Fever management with or without a temperature control device after out-of-hospital cardiac arrest and resuscitation (TEMP-CARE): A study protocol for a randomized clinical trial. Acta Anaesthesiol Scand. 2025 May;69(5):e70034. doi: 10.1111/aas.70034. PMID: 40222389; PMCID: PMC11994252. Copy Ceric A, Dankiewicz J, Hästbacka J, Young P, Niemelä VH, Bass F, Skrifvars MB, Hammond N, Saxena M, Levin H, Lilja G, Moseby-Knappe M, Tiainen M, Reinikainen M, Holgersson J, Kamp CB, Wise MP, McGuigan PJ, White J, Sweet K, Keeble TR, Glover G, Hopkins P, Remmington C, Cole JM, Gorgoraptis N, Pogson DG, Jackson P, Düring J, Lybeck A, Johnsson J, Unden J, Lundin A, Kåhlin J, Grip J, Lotman EM, Romundstad L, Seidel P, Stammet P, Graf T, Mengel A, Leithner C, Nee J, Druwé P, Ameloot K, Nichol A, Haenggi M, Hilty MP, Iten M, Schrag C, Nafi M, Joannidis M, Robba C, Pellis T, Belohlavek J, Rob D, Arabi YM, Buabbas S, Yew Woon C, Aneman A, Stewart A, Reade M, Delcourt C, Delaney A, Ramanan M, Venkatesh B, Navarra L, Crichton B, Williams A, Knight D, Tirkkonen J, Oksanen T, Kaakinen T, Bendel S, Friberg H, Cronberg T, Jakobsen JC, Nielsen N. Continuous deep sedation versus minimal sedation after cardiac arrest and resuscitation (SED-CARE): A protocol for a randomized clinical trial. Acta Anaesthesiol Scand. 2025 May;69(5):e70022. doi: 10.1111/aas.70022. PMID: 40178107; PMCID: PMC11967157. Copy Kamp CB, Dankiewicz J, Harboe Olsen M, Holgersson J, Saxena M, Young P, Niemelä VH, Hästbacka J, Levin H, Lilja G, Moseby-Knappe M, Tiainen M, Reinikainen M, Ceric A, Johnsson J, Undén J, Düring J, Lybeck A, Rodriguez-Santos D, Lundin A, Kåhlin J, Grip J, Lotman E, Romundstad L, Seidel P, Stammet P, Graf T, Mengel A, Leithner C, Nee J, Drúwe P, Ameloot K, Wise MP, McGuigan PJ, Ratcliffe A, Cole J, White J, Pareek N, Glover G, Handslip R, Proudfoot A, Thomas M, Pogson D, Keeble TR, Nichol A, Haenggi M, Hilty MP, Iten M, Schrag C, Nafi M, Joannidis M, Robba C, Pellis T, Belohlavek J, Smid O, Rob D, Arabi Y, Buabbas S, Yew Woon C, Li Q, Reade M, Delaney A, Venkatesh B, Hammond N, Bass F, Aneman A, Stewart A, Navarra L, Crichton B, Knight D, Williams A, Tirkkonen J, Oksanen T, Kaakinen T, Bendel S, Friberg H, Cronberg T, Skrifvars MB, Nielsen N, Jakobsen JC. Sedation, temperature and pressure after cardiac arrest and resuscitation-The STEPCARE trial: A statistical analysis plan. Acta Anaesthesiol Scand. 2025 May;69(5):e70033. doi: 10.1111/aas.70033. PMID: 40210585; PMCID: PMC11985327. Copy

5.2 Where will data with long-term value be archived, and for how long?

As per current Guidelines data will be stored for 15 years. A full explanation of data handling and storage are available in the full protocol: https://stepcare.org/protocol

6. Data management responsibilities and resources

6.1 Who (for example role, position, and institution) will be responsible for data management?

All local investigators will be responsible for their own data.
The full study data will be the responsibility of the management committee of the study as specified in the study protocol: https://stepcare.org/protocol

6.2 What resources will be required for your data management procedures to ensure that the data can be opened and preserved according to FAIR principles (Findable, Accessible, Interoperable, Re-usable)?

Not relevant for this study, as this is a clinical study with patient data. We can only use data based on the consent of patients and their relatives. This does not allow for public sharing.