Plan Overview

A Data Management Plan created using DMPonline

Title: Swedish Trial on Embolization of Middle Meningeal Artery versus Surgical Evacuation in Chronic Subdural Hematoma, SWEMMA

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Template: LU standard template for data management plans

Project abstract:

Studiens syfte Syftet med studien är att utröna om kärlröntgenassisterad embolisering av arteria meningea media (intervention) kan reducera reoperationsfrekvensen av kroniskt subduralhematom (KSDH) jämfört med neurokirurgisk hematomutrymning (kontroll) inom 3 månader.

Studiens design Öppen, randomiserad, prospektiv studie med blindad uppföljning vid 3 och 12 månader, samt radiologisk undersökning vid 3 mån.

Studiepopulation Patienter med tidigare obehandlat kroniskt subduralhematom som uppfyller samtliga inklusionkriterier och inga exklusionskriterier är aktuella för ettdeltagande i denna interventionsstudie.

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Swedish Trial on Embolization of Middle Meningeal Artery versus Surgical Evacuation in Chronic Subdural Hematoma, SWEMMA

1. Data description

1.1 What method of data collection will you be using?

- collecting material or generate/produce data (e.g. interviews, measurement data)

1.2 Describe how data will be collected, created or reused.

Data will be collected from medical records and questionnaires.

1.3 What type of material (physical or digital) will you use (e.g. text, images, measurement data)? In which file formats will you save your data?

text and measurements.

1.4. According to your estimation, how large is the maximum storage capacity will you need throughout the project (primary data and revisions of processed data)?

- 100 GB - 1 TB

2. Documentation and data quality

2.1 How will your data/your material be documented and described with metadata, take collection method, content, structure, standards and formats in consideration; in order for you and other researchers or computer software to read and be able to interpret the data correctly?

Data will be collected using RedCap and processed using SPSS.

2.2 How will the quality of the research data be ensured and documented (for example by repeated measurements, data entry validation etc.)?

Research data validation will be done by independent data monitoring.

3. Storage and backup

3.1 How will you ensure integrity of storage and backup of data and metadata during the research process?

Data will be backed up using Lund University secure data storage.

3.2 How is information security and access to data controlled, for example in reference to sensitive data and personal data?

Data will be backed up using Lund University secure data storage with restricted access.

4. Legal and ethical requirements

4.1 Will the project be processing personal data?

- Yes – in that case you must report this in Pulu (https://pulu.adm.lu.se)

The project is approved by the Swedish Ethical Review Authority and patients are only included after giving written informed consent.

4.2. How will you ensure that data is processed according to the regulations concerning for example personal record handling, confidentiality and intellectual property rights?

Data will be backed up using Lund University secure data storage with restricted access only to researchers involved in the project. RedCap database ensure full traceability of all data handling. All analysis will be done on pseudonymized data.

4.3. In what way will you ensure that data is handled correctly from an ethical standpoint?

Project will be conducted according to the Helsinki declaration, Swedish law and ethical standards.

4.4. Collaborative research projects involving external parties, may require an agreement between participants/principals of the study regarding processing, storage, ownership and aspects of intellectual property rights. Is this the case in your study?

- Yes, it does involve external parties

This is regulated via research agreement including agreements specifically for patient data and personal information.

5. Data sharing and long-term preservation

5.1 Will research data and/or information on data (metadata) be made publicly available?

- Yes, but only metadata

5.2 If so, how, when and where will data and/or metadata be made available? Are there any limitations (legal and/or ethical) that prevents sharing or reuse of it?

To be decided.

5.3 If you plan to make data/metadata publicly available, will you use a unique and persistent identifier (PID) such as a DOI?

Yes.

5.4 If data has been created or collected, is there a reason for keeping these forever or may they be destroyed after 10-20 years? What would the reasons be for preservation?

- My current assessment is that data probably may be destroyed.

6. Responsibilities and resources

6.1 Who is responsible for the data management and assists with the data management during the project? Who is responsible for data management, keeping of records and long-term preservation, after the project finished?

Henrietta Nittby.

6.2 What resources (cost, labor and miscellaneous costs) will be allocated to data management (including storage, backup, data sharing and long-time preservation preparation) within the project?

Cost, labor and miscellaneous costs will be covered using ALF funding and other available funding.

Planned Research Outputs

Publication - "Swedish trial on embolization of middle meningeal artery versus surgical evacuation in chronic subdural hematoma (SWEMMA)—a national 12-month multi-center randomized controlled superiority trial with parallel group assignment, open treatment allocation and blinded clinical outcome assessment"

Abstract Background Chronic subdural hematoma (cSDH) is one of the most common neurosurgical disorders and the incidence is rising. The routine treatment is neurosurgical hematoma evacuation, which is associated with recurrence rates up to 10–25%. In recent years, endovascular embolization of the middle meningeal artery (eMMA) has garnered much attention due to recurrence rates as low as < 5%. Several randomized controlled trials are planned or ongoing. In most of these trials, conventional neurosurgical treatment with or without adjunctive endovascular embolization is compared. The proposed trial aims to conduct a head-to-head comparison between neurosurgical and endovascular treatment as stand-alone treatments. Methods The trial is academically driven and funded within existing public healthcare systems and infrastructure. Patients with uni- or bilateral cSDH, presenting with mild-to moderate symptoms, and admitted to neurosurgery on clinical grounds will be offered participation. Subjects are randomized 1:1 between conventional neurosurgical treatment (control) and endovascular embolization of the middle meningeal artery (intervention). Primary endpoint is reoperation due to clinically and/or radiologically significant recurrence within 3 months. Secondary endpoints include safety, technical success rate, neurological disability, and quality of life. Discussion There are mounting retrospective data suggesting eMMA, as sole treatment or as an adjunctive to neurosurgery for cSDH, is safe and effective with a reoperation rate lower than neurosurgical hematoma evacuation alone. If randomized controlled trials confirm these findings, there is a potential for a paradigm shift in the treatment of cSDH where a minimally invasive procedure can replace open surgery in a large and oftentimes old and fragile patient cohort. Trial registration ClinicalTrials.gov, ClinicalTrials.gov Identifier NCT05267184. Registered March 4, 2022.

Planned research output details

Title	DOI	Type	Release date	Access level	Repository(ies)	File size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
Swedish trial on embolization of middle meningeal ...	10.1186/s13063-022-06842-4 ...	Publication	2022-11-08	Open	None specified		None specified	None specified	No	No