Plan Overview

A Data Management Plan created using DeiC DMP

Title: Treatment of painful osteoporotic fractures with vertebroplasty

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Project abstract:

Pain relief is a key factor in the treatment of people with vertebral fractures due to osteoporosis, since severe back pain interferes with activities of daily living. Mobilization lowers morbidity incidence and improves quality of life. Each year, 40,000 individuals in Denmark experience an osteoporotic spinal fracture. We estimate that 800 of them (5%) would benefit from vertebroplasty (injection of bone cement into the fractured vertebral body). Currently, vertebroplasty is an experimental procedure in Denmark. The purpose of this national, randomized, double-blinded clinical trial is to provide evidence for improved management of painful osteoporotic vertebral compression fractures. We propose to do this in two ways: 1) we will use stricter, better-defined eligibility criteria than in previous international trials, and we aim to demonstrate a clinically relevant, pain-relieving effect of vertebroplasty in the treated patients. 2) We will test 18F-sodium fluoride PET/MRI imaging in a subset of participants for more accurate identification of patients who will benefit from vertebroplasty. We hope that the results from this trial will provide evidence for a revision of international clinical guidelines on the treatment of osteoporotic vertebral fractures.

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Treatment of painful osteoporotic fractures with vertebroplasty

Data Collection

What data will you collect or create?

The project collects data on patients attending the research project: "Percutaneous vertebroplasty versus sham procedure for painful osteoporotic vertebral compression fractures. A randomised double blinded sham controlled clinical trial".
Participants will be enrolled in all Danish hospital departments performing PVP:

- Spine Surgery and Research, University Hospital of Southern Denmark, Middelfart
- Department of Radiology and Spine Section, Aarhus University Hospital
- Spine Section, Department of Orthopaedics, Aalborg University hospital
- Spine Unit, Department of Orthopaedic Surgery, Zealand University Hospital, Køge

DATA:
Patient Reported Outcome Messures (PROM):

- I.e. sex, age, smoking status, BMI, pain-score, function and life quality, from the national spine surgical database, DaneSpine.

Data from the patient journals:

- MRI scans

Data from surgeons:

- Surgical levels
- Complications
- Re-operations

Please ask for detailed information on each variable.
Data is collected and stored during the collection period using Topica.

How will the data be collected or created?

Blinded research staff will collect all baseline data including demographic data and outcome data, adverse events, hospital admissions and medications. All research staff will be trained to ensure data accuracy, consistency and completeness.
Most data are collected in the clinical database 'National Spine Surgical Database', DaneSpine, while data specific to this trial are stored in a separate research database.
We collect necessary patient-reported data, surgeon-reported data, information from electronic patient records and project-specific data from imaging analyses.

Documentation and Metadata

What documentation and metadata will accompany the data?

Full loggin of single data items. I.e. time of data entry, identity of the user entering data and full loggien of all subsequent handling.
Export from Topica ensures metadata is kept as e.g. STATA codebooks.

Ethics and Legal Compliance

How will you manage any ethical issues?

The project has been submitted to The Regional Commitees on Health Research Ethics for Southern Denmark. The Region of Southern Denmark is the data controller, and we have applied for their approval of the project. Information on the project will then be added to their record of processing activities according to the regulations in GDPR article 30.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

Storage and Backup

How will the data be stored and backed up during the research?

During data collection data is continually stored and updated in Topica, hosted by Region of Southern Denmark.
Permanent storing and storing on temporary data sets will be on secure data set will be on secure Topica.
The data are backed up by the host's IT department.

How will you manage access and security?

Topica allows for detailed and differentiated user access. Only project employees with need to access data will be given permission to do so.
By keeping versioned copies of all processing scripts, we ensure that our data processing steps and arguments can be followed by interested parties.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

All data are of long-term value and will be safely stored on Topica.
Participants consent to us handling the data when relevant to the project.

What is the long-term preservation plan for the dataset?

Data Sharing

How will you share the data?

Secure Topica platform made available by Region of Southern Denmark will be the site for sharing.

Are any restrictions on data sharing required?

Restrictions on data sharing:

- Access to subproject data set requires a signed contract with the project group.
- Subproject data sets will be minimized to contain only necessary variables.
- Subproject data sets will be pseudonomized if possible.

Responsibilities and Resources

Who will be responsible for data management?

Mikkel Østerheden Andersen is responsible for implementing the DMP and for each data management activity.
The resources required to deliver the DMP is Topica and SharePoint hosted by the Region of Southern Denmark.

What resources will you require to deliver your plan?