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# Treatment of painful osteoporotic fractures with vertebroplasty

*A Data Management Plan created using DMPonline*

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## Data Collection

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 spine surgical outpatient clinics at Aarhus University Hospital, Aalborg University Hospital, Odense University Hospital and Spine Center of Southern Denmark, respectively.

DATA:

Patient Reported Outcome Measures (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.

Question not answered.

## Documentation and Metadata

Full logging 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

The project has been submitted to The Regional Committees 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.

Question not answered.

## Storage and Backup

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.

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**

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.

Question not answered.

## **Data Sharing**

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

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**

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.

Question not answered.