# Intervertebral disc and curve flexibility in extension in adolescent idiopathic scoliotic patients

*A Data Management Plan created using DMPonline*

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**Template:** UMC Utrecht DMP

**Project abstract:**

Primary aim of this study is to define the correlation between sagittal alignment, the apical vertebral rotation and the coronal deformity typical in scoliosis. Secondary aim is to define the changes that occur in the IVD structures in correlation with the sagittal alignment, vertebral rotation and the coronal deformity. A total of 10 Adolescent Idiopathic Scoliosis (AIS) patients with a right convex main structural thoracic curve, between 14 and 16 years of age, who need a surgery, will be included in this study. Patients with additional spinopelvic pathology, neurological symptoms, congenital abnormalities, syndromes associated with disorders of growth, or with contra-indications for MR Imaging will be excluded.

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## 1. General features

### 1.1. Please fill in the table below. When not applicable (yet), please fill in N/A.

| | |
|---|---|
| DMP template version | 29 (don't change) |
| ABR number *(only for human-related research)* | |
| METC number *(only for human-related research)* | TBD |
| DEC number *(only for animal-related research)* | n/a |
| Acronym/short study title | WIG |
| Name Research Folder | XXX-XX. WIG |
| Name Division | Heelkundige specialisme |
| Name Department | Orthopedie |
| Partner Organization | n/a |
| Start date study | 1-05-2021 |
| Planned end date study | 1-07-2021 |
| Name of datamanager consulted* | Dax Steins |
| Check date by datamanager | 26-07-2021 |

### 1.2 Select the specifics that are applicable for your research.

- Non-WMO
- Clinical study
- Prospective study
- Observational study
- Monocenter study

## 2. Data Collection

### 2.1 Give a short description of the research data.

**First objective:** for better understanding of dynamics of the curves in AIS, the primary aim of this study is to determine if extension of the spine, through the coupling mechanism, leads to de-rotation of the vertebrae around the apex of the curve.
**Secondary aim:** define the changes that occur in the IVD in relation with the changes in curve

morphology.

A total of 10 female AIS patients with a severe right convex primary main thoracic curve, between 14 and 16 years of age, planned to undergo scoliosis surgery, will be included in this study. Patients with additional spino-pelvic pathology, neurological symptoms, congenital abnormalities, syndromes associated with disorders of growth, or with contra-indications for MR Imaging will be excluded. Therefore MR images will be collected. Patients that will meet the inclusion criteria will be approached by the local treating physician. At that time, if patients and parents/legal representatives will to participate, informed consent (IC) will be given. There will be three types of informed consent: children between 12-15, children from 16 years and parents/legal representatives. After signature by the patients/legal representatives and by the researcher IC will be kept in a binder and locked closet in a locked room at the department of Orthopaedics. Data collection will concern only the data that has a relevance in the study (MRI scan, year, type of disease). Personal data will be collected from the Electronic Patient Dossier (Hix) and will be collected in an Excel file, stored in a folder protected by a password. The image material from PACS will be pseudo-anonimyzed in Research Imaging Architecture (RIA) by the IT technical cluster image, after which the data will be moved to a protected research folder structure. The MRI scans will be evaluated with ScoliosisAnalysis, an in-house software. All the generated data will be statistically analysìzed through SPSS 26.0.0.1 and Excles, version 16.0.5161.1000. In order to  reproduce the study findings and to help future users to understand and reuse meta-data, all data will be stored.

| Subjects | Volume | Data Source | Data Capture Tool | File Type | Format | Storage space |
|---|---|---|---|---|---|---|
| Humans | 10 | EPD (HiX) | Excel | Quantitative | .xlsx | 0-10 GB |
| Human | 10 | MRI scans (PACS) | Research Imaging Architecture | Images | .dicom | 10-100 GB |

**2.2 Do you reuse existing data?**

- No, please specify

Preliminary literature review showed that there is little data available to answer our specific research question. There is thus a need to collect primary data on this topic.

**2.3 Describe who will have access to which data during your study.**

IC will be kept in a binder and locked closet in a locked room at the department of Orthopaedics. Personal data will be collected from the Electronic Patient Dossier (Hix) and will be collected in an Excel file, stored in a folder protected by a password.The image material from PACS will be pseudo-anonimyzed in Research Imaging Architecture (RIA) by the IT technical cluster image, after which the data will be moved to a protected research folder structure.

| Type of data | Who has access |
|---|---|
| Direct identifying personal data (Age, disease) | Research team with care relationship to patient, Datamanager |
| Key table linking study specific IDs to Patient IDs | PI (with care relationship to patient), Datamanager |
| Pseudonymized data | PI, Research team, Datamanager |

**2.4 Describe how you will take care of good data quality.**

All data to scoliosis characteristics and details on de-rotation in extension of the spine will be checked by one of the orthopedic surgeons. All the data will also be checked by another researcher authorized by the clinician. All data will be stored in a folder protected by a password.

| # | Question | Yes | No | N/A |
|---|---|---|---|---|
| 1. | Do you use a certified Data Capture Tool or Electronic Lab Notebook? | | NO | |
| 2. | Have you built in skips and validation checks? | | | N/A |
| 3. | Do you perform repeated measurements? | | NO | |
| 4. | Are your devices calibrated? | YES | | |
| 5. | Are your data (partially) checked by others (4 eyes principle)? | YES | | |
| 6. | Are your data fully up to date? | YES | | |
| 7. | Do you lock your raw data (frozen dataset) | YES | | |
| 8. | Do you keep a logging (audit trail) of all changes? | YES | | |
| 9. | Do you have a policy for handling missing data? | | | N/A |
| 10. | Do you have a policy for handling outliers? | | | N/A |

**2.5 Specify data management costs and how you plan to cover these costs.**

| # | Type of costs | Division ("overhead") | Funder | Other (specify) |
|---|---|---|---|---|
| 1. | Time Datamanager | x | | |
| 2. | Medical devices | x | | |
| 3. | Storage | x | | |
| 4. | Archiving | x | | |
| 5. | | | | |

**2.6 State how ownership of the data and intellectual property rights (IPR) to the data will be managed, and which agreements will be or are made.**

UMC Utrecht is and remains the owner of all collected data for this study. As it is a pilot study, data is collected in a small patient group. It may be used to find study subjects for future related studies. We are still thinking where the data will be taken when the research is finished.

## 3. Personal data (Data Protection Impact Assessment (DPIA) light)

**Will you be using personal data (direct or indirect identifying) from the Electronic Patient Dossier (EPD), DNA, body material, images or any other form of personal data?**

- Yes, go to next question

I will process personal data. I have checked the full DPIA checklist and I do not have to complete a full DPIA. I therefore fill out this DPIA light and proceed to 3.1.

**3.1 Describe which personal data you are collecting and why you need them.**

| **Which personal data?** | **Why?** |
|---|---|
| pt. demographic (age, disease) | Age is important to know/understand the behavior of the spine and how it can be flexible. If I do not know the disease, the whole study will miss essential data for the study. It is important that patients have scoliosis and not other diseases. |
| MRI images of the spine | Essential for our research aim. Detect the vertebral rotation in a scoliotic spine on MRI. |
| | |

**3.2 What legal right do you have to process personal data?**

- Study-specific informed consent

**3.3 Describe how you manage your data to comply to the rights of study participants.**

| | |
|---|---|
| Right of Access | Research data are coded, but can be linked back to personal data, so we can generate a personal record at the moment the person requires that. This needs to be done by an authorized person. |
| Right of Access | We permit participant's right of access (n=10). |
| Right of Rectification | The authorized person will give the code for which data have to be rectified. |
| Right of Objection | We use informed consents. |
| Right to be Forgotten | In the informed consent we state that the study participant can stop taking part in the research. Removal of collected data from the research database cannot be granted because this would result in a research bias. |

**3.4 Describe the tools and procedures that you use to ensure that only authorized persons have access to personal data.**

We use the secured Research Folder Structure that ensures that only authorized personnel has access to personal data, including the key table that links personal data to the pseudoID.

**3.5 Describe how you ensure secure transport of personal data and what contracts are in place for doing that.**

We will not transport any personal data outside the UMCU network drives

## 4. Data Storage and Backup

**4.1 Describe where you will store your data and documentation during the research.**

The digital files will be stored in the secured Research Folder Structure of the UMC Utrecht. We will need +/- 50 GB storage space, so the capacity of the network drive will be sufficient. Paper dossiers will be stored safely in a locked cabinet in a locked room in the UMC Utrecht. A project specific procedure is in place for access to the paper dossiers. Documentation of this procedure is stored in the Research Folder Structure.

**4.2 Describe your backup strategy or the automated backup strategy of your storage locations.**

1. All (research) data is stored on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT).
2. During data collection, automatic backups will be made in the electronic data storage tool

of radiological images RIA. Upon completion of data collection, all data are exported and saved in the Research Folder Structure where they are automatically backed up by the UMC Utrecht backup system.

# 5. Metadata and Documentation

### 5.1 Describe the metadata that you will collect and which standards you use.

Metadata will be collected and will be kept in a binder in a locked closet in a locked room and in a folder protected by password. The data will be delivered including a data dictionary. For every variable this data dictionary contains an explanation of the values.

### 5.2 Describe your version control and file naming standards.

We will distinguish versions by indicating the version in the filename of the master copy by adding a code after each edit, for example V1.1 (first number for major versions, last for minor versions). The most recent copy at the master location is always used as the source, and before any editing, this file is saved with the new version code in the filename. The file with the highest code number is the most recent version. Every month, we will move minor versions to a folder OLD. The major versions will be listed in a version document (projxVersDoc.txt), stating the distinguishing elements per listed version

# 6. Data Analysis

### 6 Describe how you will make the data analysis procedure insightful for peers.

I have written an analysis plan in which I state why I will use which data and which statistical analysis we plan to do in which software. The analysis plan is stored in the project folder, so it is findable for my peers. We'll use SPSS, version 25.0.0.2, for statistical analysis of the data.

# 7. Data Preservation and Archiving

### 7.1 Describe which data and documents are needed to reproduce your findings.

The data package will contain: the raw data, documentation on the research methodology (data manuals, metadata compilation, MRI protocol), project proposal, approval for human-related studies, research team, the study protocol describing the methods and materials, the MRI images, the script to process the data, the scripts leading to tables and figures in the publication, a codebook with explanations on the variable names, a ‘read_me.txt’ file with an overview of files included and their content. These are all the data and documentation that will

be used in this research project. All data will be stored in a protected folder at the UMC and will be available under restriction (see section 8.2) for 15 years. This section can be updated if more information/data come up from the MRI images during analysis.

**7.2 Describe for how long the data and documents needed for reproducibility will be available.**

In view of the regulation for Clinical Trials, I need to store all data for at least 15 years with the goal to be able to go back to patient level.

**7.3 Describe which archive or repository (include the link!) you will use for long-term archiving of your data and whether the repository is certified.**

After finishing the project, the data package will be stored at the UMC Utrecht Research Folder Structure and is under the responsibility of the Principal Investigator of the research group. When the UMC Utrecht repository is available, the data package will be published here.

**7.4 Give the Persistent Identifier (PID) that you will use as a permanent link to your published dataset.**

To be determined.

## 8. Data Sharing Statement

**8.1 Describe what reuse of your research data you intend or foresee, and what audience will be interested in your data.**

The raw data can be of interest for other researchers or for spin off projects.

**8.2 Are there any reasons to make part of the data NOT publicly available or to restrict access to the data once made publicly available?**

- Yes (please specify)

As the data is privacy-sensitive, data will be available under restriction by sending an email to the corresponding author. The study subject signing the Informed Consent will give permission for storage and usage of the data. Methodology, MRI protocol, study protocol and data will be stored in a protected folder at the UMC. In the event that peers like to reuse our data this can only be granted if the research question is in line with the original informed consent signed by the study participants and/or legal representatives. Every application therefore will be screened upon this requirement. If granted, a data usage agreement is signed by the receiving party.

**8.3 Describe which metadata will be available with the data and what methods or software tools are needed to reuse the data.**

All data and documents in the data package mentioned in 7.1 will be shared under restrictions.

**8.4 Describe when and for how long the (meta)data will be available for reuse**

To be determined in the future.

**8.5 Describe where you will make your data findable and available to others.**

To be determined in the future.