The role of the intervertebral disc in the progression of adolescent idiopathic scoliosis: a prospective study using magnetic resonance imaging.

Published: 24-11-2016
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Primary Objective: This study aims to detect early changes in the morphology and MRI signal of the IVDs during scoliosis progression.Secondary Objective(s): 1. To correlate the findings on MR -imaging with patient-reported outcome measurements...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational non invasive

Summary

ID

NL-OMON50461

Source
ToetsingOnline

Brief title
MRI disc in scoliosis

Condition

- Bone disorders (excl congenital and fractures)

Synonym
Scoliosis, three-dimensional deviation of the spinal axis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: AO Spine

Intervention

Keyword: Adolescent idiopathic scoliosis, Intervertebral disc, MRI

Outcome measures

Primary outcome

Each MR scan will consist of a standard sagittal-only T2W, developed for IVD imaging. The IVDs of the spine between T1 and S1 will be scanned. The different parameters will be measured semi-automatically.

The primary study parameters are changes in MRI timing, sensitivity, dynamic range, spatial distribution and morphological changes of the IVD during AIS progression.

Secondary outcome

The secondary parameters are:

1. Correlation of the findings on MR-imaging with patient-reported outcome measurements using the SRS-22 questionnaire

Study description

Background summary

Adolescent idiopathic scoliosis (AIS) is a three-dimensional (3-D) deformity not only affecting the spine but the entire trunk. Significant scoliotic deformities may have serious adverse effects including cardio-respiratory problems, back pain, cosmetic concerns, social and psychological problems and the financial costs of treatment. Despite many years of extensive research, the exact aetiology remains unclear. Another topic of discussion is the ability to

predict (rapid) curve progression; there are no prognostic factors identifying the group at risk for rapid progression.
Changes in the mechanical properties of the intervertebral disc (IVD) have been associated with onset and progression of AIS. The IVD, the most important stabilizer of the spine, consists of a fibrocartilaginous ring called the annulus fibrosis and a gel-like core, the nucleus pulposus (NP), which mainly consists of proteoglycans and collagen. To date, some changes in the IVD have been reported in progressive scoliosis. Mostly in terms of tissue composition of scoliotic discs removed during surgery. Recent data showed at least three times more deformation in the IVD compared to the vertebral body in all three planes of a scoliotic curve. These findings suggest that AIS is mainly a 3-D deformity of the IVD and that abnormal vertebral growth, according to Hueter-Volkmann*s law, is a consequence rather than a cause of AIS. This greater contribution of the IVD to the 3-D deformity is likely caused by lower stiffness of the intervertebral fibrocartilage as compared to the bony vertebrae.
However, research into the changes occurring within the IVDs of the scoliotic spine is limited by the lack of proper animal models and the impossibility of analyzing human tissue during progression. This problem can be overcome by mapping the changes in the IVDs using novel MR-based imaging, determining the composition and integrity of cartilaginous tissues, without any invasive procedures or radiation involved.

Study objective

Primary Objective:
This study aims to detect early changes in the morphology and MRI signal of the IVDs during scoliosis progression.

Secondary Objective(s):
1. To correlate the findings on MR -imaging with patient-reported outcome measurements using the SRS-22 questionnaire

In total we will make three MR scans of each patient; t=0, t=6 months.

Study design

Prospective cohort study.

Study burden and risks

The results from this study will provide us with more knowledge about the role of the IVD in the progression of AIS and may also shed light on its potential role in the development of this deformity. Data on the MRI-based changes in the IVD occurring in AIS might be used in the future as a prognostic factor for children who already have AIS, and possibly intervene earlier with

non-operative treatments in which -to be developed- regenerative medicine strategies may be employed. There are no noteworthy risks associated with participating in this study, and no invasive procedures or contrast administration will be performed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Patients diagnosed with adolescent idiopathic scoliosis
- Presence of right convex main thoracic structural curve, either in Lenke type 1 or 2;
- Female gender
- Between 10-16 years of age

- Cobb*s angle 20-40 degrees

Exclusion criteria

- Skeletal maturity
- Presence of any additional spine pathology such as spondylolysis or -listhesis, M. Scheuermann, congenital spinal abnormalities, spinal tumors and spinal trauma
- Previous spinal surgery
- Neurological symptoms, deficits or pathology
- Syndromes associated with disorders of growth
- Any contra-indication for MR Imaging

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-12-2019
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	24-11-2016
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	24-07-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	22-08-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-05-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-07-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-01-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-01-2021
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL58104.041.16