LONG-TERM EFFECT OF SELECTIVE THORACIC FUSION ON LUMBAR DEGENERATIVE DISC DISEASE IN IDIOPATHIC SCOLIOSIS

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Observational invasive

Summary

ID

NL-OMON54795

Source
ToetsingOnline

Brief title
DISCUS study

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Bronchial disorders (excl neoplasms)

Synonym
curved spine, scoliosis

Research involving
Human

Sponsors and support

Primary sponsor: Orthopedie
Source(s) of monetary or material Support: OPIS beurs en OLVG wetenschapsbeurs

Intervention

Keyword: -Adolescent idiopathic scoliosis, -AIS, -Bracing, -Degenerative disc disease, -Long-term outcome, -Selective thoracic fusion, -Spinal osteoarthritis

Outcome measures

Primary outcome

Signs of osteoarthritis can be quantified by radiography in 2 directions

(Posterior-Anterior and

lateral) . Signs of osteoarthritis will be classified by Pathria,

Kellgren-Lawrence and Weishaupt

classification.

Signs of DDD will quantified by the total number of degenerated disc per

subject and the

proportion of degenerated discs. In addition, proportion of discs with

Schmorl*s nodes, discs

herniation and discs with inflammatory end plate changes will be determined.

Secondary outcome

The radiological results may be correlated to patients demographics, curve

types (e.g. Lenke

classification) , size of the remaining curve, parameters of spinal balance or

clinical outcomes of our

BASIS study (a previous study of ours which evaluated long-term clinical

self-reported outcomes

with the following questionnaires: Health related quality of life: SF-36,

EQ-5D, SRS-22& and low

back pain: Oswestry Disability Index and visual analogue scale)

The spirometry will be compared to the one performed during childhood to

examine the difference

in pulmonary functioning over the years.

The DISCUS study protocol describes the inclusion of three patient groups: group 1 is operated on and had a curvature of 45-55 degrees before surgery (after correction, their curvature measures 20-25 degrees), group 2 is non-operated and has a curvature of approximately 20-25 degrees at the end of growth, and group 3 is non-operated with a curvature of 45-55 degrees at the end of growth (similar to group 1 before surgery). Groups 1 and 3 have already completed all examinations, and interim results show minimal disc degeneration in group 3 on the MRI scan. Therefore, we expect that MRI scans of group 2 (with less scoliosis than group 3) will not provide additional value, and we intend to refrain from including this patient group to avoid subjecting them to unnecessary research.

However, we observe significant scoliosis progression in group 3 (classified as severe scoliosis with a Cobb angle of 45 degrees) based on the new X-rays. We would like to expand this research group by obtaining X-rays of more patients with non-operated scoliosis and a curvature of 45 degrees. This population has

previously participated in the study on Health Related Quality of Life (BASIS WO15.017) and has already provided consent to be approached for follow-up research. This group consists of 22 patients.

Expanding the sample size of scoliosis patients from "Group 3" aims to provide valuable insights into the curvature progression of non-operatively treated scoliosis after growth completion. Before obtaining new X-rays, we will inquire whether patients have had X-rays taken at another hospital in the past 5 years and if we may request those images. If available, it will not be necessary to take new X-rays.

The findings will contribute to a better understanding of the long-term outcomes and can support clinical decision-making for this patient population

Study description

Background summary

Scoliosis is the most common deformity of the spine affecting approximately 2-3% of children younger than 16 years of age4. In 0.3-0.5% of the children, the spinal curve becomes progressive and requires treatment. It is a complex three-dimensional deformity of the spine that presents during childhood, and usually worsens during adolescence. It is ten times more common in female than in males. The most common scoliosis is the idiopathic scoliosis which means there is no definite etiology. The curve can cause pain, shortness of breath and fatigue on young age. Most children with scoliosis do not have complaints of the deformity. The treatment of the

asymptomatic adolescent scoliosis patients aims to prevent future problems, like osteoarthritis of
the spine and degenerative disc disease. The goal of the treatment is a curve with a angle of less
than 45 degree at skeletal maturity. Natural history studies indicate that curves bigger than 45
degree tend to progress after skeletal maturity due to gravity. If curves become larger, the more
the spine is out of his equilibrium, which cause an asymmetric force on spinal joints en discs.
Besides osteoarthritis of the spine, major curves can cause nerve, heart, lungs and psychological
problems.
Treatment of idiopathic scoliosis attempts alter the natural history of the disease. The only proven
conservative treatment is brace treatment. Children have to were the brace during a few years of
their growth spurt 20 hours a day and is only effective in rapidly growing immature patients with a
mild spinal curvature (25-45 degrees). Severe curves over 45 degrees are an indication of surgical
treatment. Surgical treatment does not completely cure scoliosis, but helps to correct the curve by
approximately 50% and manage curve progression by fusing a large area of the spine to prevent
further progression. The aim of the brace is to stop progression and maintain the curve below 45
degrees thereby leaving the patient with a deformity with lesser risk of problems in later life. A
recent randomized controlled trial confirmed the efficacy of bracing in idiopathic scoliosis with
level-1 evidence by showing a significant reduction of curve progression and subsequent reduction
of the need for surgery.
Despite treatment in adolescence, few patients experience problems during adolescence.
Treatment of the asymptomatic adolescent scoliosis patients aims to prevent future problems.
Many adult scoliosis patients experience back pain caused by osteoarthritis and degenerative disc
disease4. Backpain and poor self-image due to the cosmetic deformity can result in social and
psychological problems. Although scoliosis treatment is focused on long-term problems, only few
scoliosis studies have studied the long term outcomes of current surgical and non-surgical
treatments. There is evidence that surgery of the primary curve may have a

short term protective
effect on the unfused discs below the fusion area, possibly because they are more symmetrically
loaded after surgery than before5,6. However it will stiffens a part of the spine. Because of the long
fused thoracic segment, more load is centered on the lumbar segment of the spine in spinal
movements, which may cause increased stress on zygapophysial joints and intervertebral discs. This
may cause progression of degenerative osteoarthritis en degenerative disc disease.
Furthermore, last year we examined the influence of the thoracic curve on the pulmonary function
in patients with scoliosis. A meta-regression analysis showed that pulmonary function (FEV1 and
FVC) in children and adolescents decreases with 1% per 2.5 to 3 degrees increase of the Cobb
angle. Information on the long-term outcomes of the influence of scoliosis on pulmonary function
is scarse, therefor we would like to re-do the spirometry to compare the outcomes with the
spirometry during childhood.

Study objective

Our overall aim of the our project is to evaluate the long-term treatment effects of bracing and
surgery in patients with adolescent idiopathic scoliosis, with a minimum 25 years follow-up.
Secondly, to determine clinical and/or radiological predictors to predict curve progression.
1) What is the prevalence and degree of osteoarthritis and degenerative disc disease in the lumbar
spine using radiographical imaging (i.d. Radiography and MRI)?
2) Is there a relation between these radiological findings and long-term clinical outcomes (e.g.
backpain, quality of life) in these patient group?

Study design

The study is cross-sectional cohort study and enrolls scoliosis and control patients. It will be
performed at the department of Orthopedics of the OLVG in Amsterdam. Patients meeting the
inclusion and exclusion criteria will be selected from the OLVG scoliosis database. Patients will be

contacted by telephone. After providing them with information on the study, patients will be asked
if they are willing to participate after 2 weeks of consideration time. If a patient gives approval, a
patient information letter and an informed consent form will be send to them. After completing the
informed consent, the X-ray of their full spine and MRI scan of their lumbar spine will be scheduled.
After the scan, the patients will be contacted by phone to discuss the outcome of their scans.
In accordance with our research protocol, we will inquire whether patients have undergone spinal radiography within the past five years prior to obtaining a new radiograph. In the event that such a radiograph exists, we will seek consent to retrieve and utilize these images for our research purposes, particularly in cases where the radiograph was conducted at a different medical facility.

Study burden and risks

For the study, the patient have to come once to the hospital. During this visit two X-rays and one
MRI of the lower back will be taken. Thereby, a spirometry will be performed.

The patient*s burden from the study consists of one extra visits of 2,5 hours to the OLVG hospital. It involves a standard anterior-posterior & lateral radiographs and an MRI scan of the lumbar spine. The patient*s burden from the study consists of one visit to the OLVG hospital. After analyzing the images, the patients will be contacted by phone to discuss the outcome of their scans. The questionnaires are already completed as part of a previous BASIS study in OLVG hospital.
There are no risks associated with the MRI scan of the lumbar spine.
The risk of the single upright AP and lateral radiograph of the lumbar spine will be limited. The effective radiation dose for a AP Lower Back image is 680 µSv.32 The additional annual radiation dose is limited if the natural annual exposure of 2 mSv is considered and will do the patient no harm.33 The International Commission on Radiological Protection categorizes the corresponding level of risk qualitative due to radiation as *low* with a quantitative risk of about 1 in 10.000 or less.
Radiation safety measures, such as using appropriate lead shielding and minimizing the number of X-ray images taken, are employed to keep the radiation dose as low as reasonably achievable (ALARA principle). Additionally, healthcare providers follow specific protocols and equipment standards to ensure that radiation doses are within safe limits.
Overall, a single X-ray of the spine in the AP and Sagittal views is generally considered to be safe and compliant with Dutch laws and regulations on medical radiation exposure. As with any medical procedure, healthcare providers prioritize patient safety and ensure that radiation doses are kept as low as

reasonably achievable while providing valuable diagnostic insights

The risk associated with a MRI (Magnetic Resonance Imaging) scan of the lumbar spine is generally considered to be very low. MRI uses a powerful magnetic field and radio waves to create detailed images of the internal structures of the body, including the spine. Unlike other imaging techniques that use ionizing radiation (such as X-rays or CT scans), MRI does not expose the patient to ionizing radiation, which is a significant advantage in terms of safety. There are some considerations to keep in mind:
- Claustrophobia: Some individuals may experience claustrophobia (fear of enclosed spaces) while inside the MRI machine, which can lead to discomfort or anxiety during the procedure.
- Metallic objects: MRI uses a strong magnetic field, and therefore, it is essential to remove all metallic objects from the body, including jewelry, watches, and certain medical implants or devices, as they can be attracted to the magnet or cause interference with the scan.

Contacts

Public
Selecteer

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NL
Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

For all patients
• Patients with adolescent idiopathic scoliosis
• Lenke type 1 scoliosis
• at least 25 years skeletal matureGroup 1
• Not treated surgicallyGroup 3
• Curve size matching curve size of group 1 before operation
• Not treated surgically

Exclusion criteria

• Inadequate knowledge of Dutch language
• Other forms of scoliosis (e.g. neuromuscular or congenital scoliosis)
• Inability to undergo an MRI scan (claustrophobia, pacemaker, etc)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-12-2021
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	03-10-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-10-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-12-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-04-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-09-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL59162.100.17