Adolescent idiopathic scoliosis: fixation of the back by screw or hook fixation?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27556

Source
Nationaal Trial Register

Brief title
FIXIT

Health condition

adolescent idiopathic scoliosis, spondylodesis, spinal fusion, idiopathische scoliose, spondylodese

Sponsors and support

Primary sponsor: Erasmus Medical Center, department of orthopaedic surgery, Rotterdam
Source(s) of monetary or material Support: Zimmer Biomet

Intervention

Outcome measures

Primary outcome

The primary study parameter is difference in coronal Cobb angles after two years of follow-up.

Secondary outcome

- vertebral rotation angles

- number of complications and/or revisions

- pulmonary function measures

- vital capacity (VC)

- absolute and percent predictive
forced vital capacity (FVC)

- absolute and percent predictive
forced expiratory volume in 1 second

- FEV-1/VC ratio

- lung volume

- preoperative and postoperative clinical photographs

- questionnaire results (SRS-30, CHQ-CF87, CHQ-PF50)

- CT evaluation of accuracy of pedicle screw placement within the pedicle

- serum measurements of cobalt and chromium at seven certain moments

Study description

Background summary

Surgical treatment of progressive or severe adolescent idiopathic scoliosis (AIS) often consists of posterior spinal fusion. There is still no consensus on the preferred instrumentation technique. Recently, the concept of using all pedicle screw instrumentation has been popularized. Thoracic pedicle screws are generally believed to give a better correction of coronal Cobb angle and vertebral rotation, and to have a higher pull-out strength. However, these studies have poor to fair methodological quality, and at least the clinical relevance of these findings is not clear. In our hospital we haven been using a proximal hook claw construct for years with good results. We hypothesize that proximal fixation of the spondylodesis with a pedicle screw construct gives better coronal Cobb angle correction with less loss of correction compared to a hook claw construct.

Besides, most spinal implants consist of cobalt chromium alloys and titanium. In hip replacement surgery, there are many recent studies reporting elevated serum cobalt and chromium levels in metal-on-metal arthroplasties, which can be potentially dangerous. In

spinal surgery, only cross-sectional studies have been carried out with regard to this phenomenon. However, elevated serum metal ion levels can be of importance, because exposure to nonphysiologic levels of chromium can result in genotoxicity, mutagenicity, impaired reproductive function, and infertility.

Study objective

Proximal fixation of the spondylodesis with a pedicle screw construct gives better coronal Cobb angle correction with less loss of correction compared to a hook claw construct.

Study design

pre-operatively, perioperatively, and postoperatively at 6 weeks, 3 months, 6 months, 1 year and 2 years.

Intervention

Surgical posterior instrumentation and fusion, in accordance with the standard. There will be a randomization between proximal fixation of the instrumentation with a hook claw construct or with a pedicle screw construct. Both surgical treatments are valid options in the standard care of patients with adolescent idiopathic scoliosis.

Contacts

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Eligibility criteria

Inclusion criteria

- adolescent idiopathic scoliosis

- coronal Cobb angle of >50°

- coronal Cobb angle of >40° in the skeletally immature patient

- progressive scoliosis despite bracing (at least 5 degrees annually)

- age at surgery between 8 and 20 years

- structural thoracic curves (Lenke curve type 1-4)

- informed consent

Exclusion criteria

- neuromuscular scoliosis

- congenital scoliosis

- planned for posterior fusion in combination with anterior release, i.e. severe hyperkyphosis

- prior spinal surgery

- intraspinal pathology

- not able to speak or read Dutch

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2016
Enrollment:	60

Type:	Anticipated

Ethics review

Positive opinion

Date:	22-01-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43852
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5552
NTR-old	NTR5674
CCMO	NL36436.078.11
OMON	NL-OMON43852

Study results