Dorsal spondylodesis in adolescent idiopathic scoliosis: proximal fixation with screws versus claw construct

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON43852

Source
ToetsingOnline

Brief title
Proximal fixation technique in dorsal spondylodesis

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
scoliosis; lateral curvature of the spine

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Biomet

Intervention

Keyword: Dorsal spondylodesis, hook claw construct, scoliosis, thoracic screws

Outcome measures

Primary outcome

Difference in coronal Cobb angles after two year of follow-up.

Secondary outcome

Is there a difference in

• coronal Cobb angle correction direct postoperatively;

• correction loss during (at least) two years of follow-up;

• vertebral rotation correction;

• complication and/or revision rate;

• effects on pulmonary function;

• postoperative lung volume;

• cosmetic outcomes;

• subjective questionnaire results (including patient*s satisfaction);

between proximal pedicle screw fixation and proximal hook claw fixation?

- Is there a correlation between the extent of scoliosis correction and the

degree of patient satisfaction?

- How is the accuracy of thoracic pedicle screw placement?

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 use for years a proximal hook claw construct 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.

Study objective

The main objective is to compare the coronal Cobb angle correction of proximal hook claw fixation versus proximal pedicle screw fixation after two years of follow-up. The secondary objectives of the study are: comparison of coronal Cobb angle correction direct postoperatively, coronal Cobb angle correction loss after two years, vertebral rotation correction, complication and revision rate, pulmonary function, postoperative lung volume, cosmetic outcomes, and subjective questionnaire results in proximal hook claw versus screw fixation, assessment of the correlation between the extent of scoliosis correction and the degree of patient satisfaction, and determination of the accuracy rate of thoracic pedicle screw placement.

Study design

Single-blind prospective randomized controlled clinical trial with a follow-up of two years postoperatively.

Intervention

Surgical posterior instrumentation and fusion, in accordance with the standard. There will be randomized between proximal fixation of the instrumentation with a hook claw construct or with a pedicle screw construct.

Study burden and risks

Additional to routine treatment are two low dose spirometrically controlled CT*s (pre- and postoperatively), two clinical photographs of the back (pre- and postoperatively), one pulmonary function test postoperatively, and three questionnaires which has to be filled in pre- and postoperatively. Compared to routine treatment one less conventional radiograph is required because it is replaced by a CT. It is not known whether proximal hook or screw fixation truly

has more potential disadvantages or risks.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

As according to Bridwell:
- 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

- Lenke curve type 1-6
- 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-02-2016
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	23-12-2011
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-12-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-09-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-01-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27556
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL36436.078.11
OMON	NL-OMON27556