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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27556

Bron
Nationaal Trial Register

Verkorte titel
FIXIT

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus Medical Center, department of orthopaedic surgery, Rotterdam
Overige ondersteuning: Zimmer Biomet

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

A. Willems
Rotterdam
The Netherlands

Wetenschappelijk

A. Willems
Rotterdam
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2016
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-01-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43852
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten