Pilot study on effectiveness and safety of Shape Memory Scoliosis Correction Instrument

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Primary Objectives:• show effectiveness of the SMSC instrument in 3D correction of the spine prior to placement of the implants.The hypothesis is that to achieve de-rotation of the spine without failure of the pedicle screws, de-rotation has to be...

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

Summary

ID

NL-OMON36472

Source
ToetsingOnline

Brief title
Scoliosis Correction Instrument

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Nervous system, skull and spine therapeutic procedures

Synonym
scoliosis; sideways bending of the spine

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: biomechanics, correction, scoliosis, surgery

Outcome measures

Primary outcome

Study parameters/endpoints

Main study parameter/endpoint

• De-rotation measured at the middle two vertebra connected to the instrument

should be > 50% during surgery.

• Post-surgery Rib Hump reduction should be > 20%

Secondary outcome

Not applicable

Study description

Background summary

1. INTRODUCTION AND RATIONALE

The main reason for patients to undergo surgical intervention for Idiopathic Scoliosis is to reduce Rib Hump.
The standard procedure for correction of the deformity will reduce the lateral and kyphotic deformation but does not correct the rotation of the vertebrae whereas the main influence on hump reduction is the de-rotation of the spine. This lack of de-rotation is not due to the implant which fixates the vertebrae but due to the limited possibilities of the current instruments available to correct the deformity prior to placing the rods.
A recent article by Cheng et al.[1] showed that in the current standard procedure the forces during de-rotation exerted by the instruments on the pedicle screws are high and can cause failure of the vertebra.

This pilot study is set up to asses clinically that the Shape Memory Scoliosis Correction (SMSC) Instrument is capable of simultaneous 3D correction on all

levels prior to placing the implants as used in the standard procedure.

Compared to the standard procedure the only difference is the instrument used to correct the deformity prior to placement of the rods. All implants (rods and pedicle screws) are the same as in the standard procedure.

The advantages of the SMSC instrument over the standard instruments:
• Simultaneous 3D correction vs 2D correction
• Simultaneous correction on all levels vs correction per level
• Locking of the desired correction until the rods are placed
These advantages combined should result in correction of the deformation including de-rotation and thereby result in a decrease of the rib hump

The SMSC instrument has been tested with good results on its safety and function in mechanical tests and functional tests on sawbone.
There is no literature found on an instrument to correct Scoliotic deformation simultaneous in 3D on all levels, so there is no prior data on this type of correction.
Due to the specific behaviour of the human spine it is only possible to show its effectiveness during a clinical trial.
[1] Cheng I, Hay D, Iezza A, Lindsey D, Lenke LG., Biomechanical analysis of derotation of the thoracic spine using pedicle screws., Spine, 2010 May 1;35(10):1039-43.

Study objective

Primary Objectives:
• show effectiveness of the SMSC instrument in 3D correction of the spine prior to placement of the implants.
The hypothesis is that to achieve de-rotation of the spine without failure of the pedicle screws, de-rotation has to be done simultaneous over all levels and in combination with lateral and kyphotic correction to minimize increased correction forces due to interaction between the separate vertebra.

• Show significant rib hump reduction after the standard procedure with the use of the SMSC instrument.
The hypothesis is that there is no significant rib hump reduction without de-rotation of the spine

Study design

STUDY DESIGN

The study is set up as an observational study: a case series of 15 subjects.

The duration of the study is 1 year.
The follow-up is conform the standard procedure and is not included in the trial.
The data to confirm the objectives is collected during and immediately after the surgery

The study is performed at the UMCG

Study burden and risks

Burden: Time in surgery increased by approx. 20 minutes.

Risks associated with the investigational product: If the investigational product does not correct as foreseen or can not be fitted to the patient it will be removed and the standard instruments will be used. Risk for the patient is an additional 20 minutes operating time

Benefit: Patient will have a higher rate of reduction of the deformity compared to the use of the standard instruments.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adolescents between 13 and 25 year suffering from idiopathic scolioses and listed for surgical intervention.4.2 Inclusion criteria
• Cobb Angle > 40*
• King I-V

Exclusion criteria

Exclusion criteria
• Severe scoliosis, very stiff spine (minimal correction on bending films)
• Reduced bone quality (osteoporosis, decalcification)
• Fractures
• Tumors
• Spondylolistheses
• Active infection
• Allergy to Titanium or it*s alloys

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2011
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	16-03-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL33390.042.10