Evaluation of the safety and effectiveness of the MID- C system in adolescent idiopathic scoliosis.

No registrations found.

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

Summary

ID

NL-OMON21786

Source
NTR

Health condition

Surgical treatment of adolescent idiopathic scoliosis (AIS).

Sponsors and support

Primary sponsor: VU University Medical Center, Amsterdam, The Netherlands
Source(s) of monetary or material Support: VU University Medical Center, Dpt. of Orthopedic Surgery, Amsterdam, The Netherlands

Intervention

Outcome measures

Primary outcome

1. Correction of primary curve Cobb angle at 6 months follow-up (percentage and absolute degrees).

Secondary outcome

Safety:

1. Curve progression above or below the implant over time at all follow-ups;

2. Vertebral rotation based on Bunnell Scoliometer;

3. Vertebral rotation based on AP X-ray using the Nash and Moe method [7], and;

4. (Serious) adverse event.

Effectiveness:

1. Patient reported outcome (SRS-22);

2. Correction of primary curve Cobb angle to <35 degrees Cobb angle at 6 months follow-up;

3. Correction of primary curve Cobb angle over time at all follow-ups, and;

4. Correction of secondary curve Cobb angle over time at all follow-ups.

Study description

Background summary

The current gold standard for the treatment of adolescent idiopathic scoliosis is bracing in an early stage. If the curve progresses the scoliosis can be surgically corrected using posterior spinal instrumentation and fusion. Bracing therapy has a large impact on young adolescents resulting in low therapy compliance and the current surgical technique is extensive and irreversible. It is accompanied with risks of neurological damage, wound infection and a major decrease in spinal mobility.
The ApiFix system is a novel less invasive short segment pedicle screw based instrumentation. It is connected to the spine around the apex of the main scoliotic curve. The ApiFix system has a ratchet mechanism. By performing specific spinal exercises the ratchet is activated which results in device elongation. This results in a decrease of the scoliotic curvature. Due to the poly-axial joints, correction of the scoliosis is achieved without fusion. This study is designed to evaluate the effectiveness and safety of the ApiFix (MID-C) System. Patients will be recruited in The Netherlands.

Study objective

This study is designed to evaluate the effectiveness and safety of the ApiFix (MID-C) System.

Study design

2 weeks, 6 weeks, 12 weeks, 6 months, 12 months, 24 months postoperatively.

Intervention

The spinal deformity of the patients will be surgically corrected using the ApiFix system and sequential correction exercises.

Contacts

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Eligibility criteria

Inclusion criteria

1. Adolescent AIS patients (12 years - 17 years old);

2. Standing X-ray: 40 to 55 degrees Cobb angle, Lenke type 1 or 5, Risser stage 1-4;

3. Lateral bending X-ray: primary curve should be reduced to <35 degrees Cobb

angle after lateral bending;

4. Subject has good general health;

5. Subject and both subject‘s guardians/legal representatives are willing to sign a written informed consent form;

6. Vertebral rotation <15 degrees (based on Bunnell Scoliometer), and;

7. Compliance for exercise therapy (based on verbal confirmation of patient)

Exclusion criteria

1. Other non-idiopathic form of scoliosis;

2. Primary curve Cobb angle >55 degrees;

3. AIS which is not defined as Lenke type 1 or 5;

4. Previous spine surgery;

5. Known allergy to titanium;

6. Active systemic disease, such as AIDS, HIV, or active infection;

7. Systemic disease that would affect the subject’s welfare or overall outcome of the study, or;

8. Mentally compromised.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-08-2015
Enrollment:	33
Type:	Anticipated

Ethics review

Positive opinion Date:	15-07-2015
Application type:	First submission

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
NTR-new	NL5162
NTR-old	NTR5302
Other	Institutional Review Board, VU University Medical Center, Amsterdam, The Netherlands : 2015.223

Study results