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

Published: 08-07-2015
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This study is designed to evaluate the effectiveness and safety of the MID-C System.

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

Summary

ID

NL-OMON43676

Source
ToetsingOnline

Brief title
The ApiFix system for the treatment of adolescent idiopathic scoliosis

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Bone and joint therapeutic procedures

Synonym
Spinal curvature

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Adolescent idiopathic scoliosis, Effectiveness, MID-C/ApiFix system, Safety

Outcome measures

Primary outcome

Effectiveness:

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

Adolescent idiopathic scoliosis (AIS) is a complex three-dimensional deformity of the spine, which can cause significant physical and psychological problems. Currently there are two treatment options available for adolescent idiopathic scoliosis (AIS): bracing and spinal correction of the scoliosis with spinal fusion.
Bracing is indicated for curves between 25 and 40 degrees Cobb angle in patients with significant growth potential (Risser stage 1-2). The treatment causes significant discomfort and problems with appearance for this young patient group, resulting in compliance problems and thus a negative effect on treatment success. Long spinal fusion is indicated for curves greater than 45 degrees Cobb angle preferably when patients have stopped growing but for reasons of the magnitude of the curve in some cases also during growth. During this procedure, the curve is corrected and the spine is fused stiff using screws and rods. This is complex and invasive surgery and significant complication rates are reported up to 5.1%.
ApiFix LtD has developed a novel spinal implant for a less invasive surgical treatment of AIS: the MID-C system. It is indicated for patients with a scoliosis of 40 to 55 degrees Cobb angle. Thus, it bridges the gap between the indication for bracing (25 to 40 degrees) and posterior fusion (>45 degrees) and overlaps the indication for both bracing and posterior fusion. The MID-C system is a novel scoliosis correction device, which provides a gradual correction of the deformity. This gives the skeletal and soft tissues the opportunity to accommodate incremental correction. The MID-C system has several potential benefits: smaller scar, quicker healing period and better spine mobility over the years.

Study objective

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

Study design

This study is a prospective, open label, non-randomized cohort study.

Intervention

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

Study burden and risks

As compared to standard posterior fusion surgery, treatment with the MID-C is expected to have significantly less postoperative physical burdens for the patient. Postoperative pain management is similar to the protocol of traditional spinal fusion surgery. Compared to traditional treatment, patients

have one extra follow-up visit, two extra x-rays and three extra clinical photographs.
Based on the pre-clinical tests, clinical experience with 37 patients (operated outside The Netherlands), and the risk analysis documents we conclude that the risks are expected to be low. Potential risks of gradual correction with MID-C as compared to standard posterior fusion are: 1) untreated compensatory curve may not be corrected, 2) curve progression above and below the implant, 3) implant failure (breakage or loosening) and 4) untreated vertebral rotation may not be corrected.
The potential benefits of surgical correction with the MID-C system as compared to traditional fusion surgery are as follows: less impaired (more physiological) spinal movement, gradual correction of the deformity and a decreased risk of surgery associated complications due to the minimally invasive nature of the procedure (i.e. shorter incision, shorter surgery time, less blood loss, less infection risk and decreased risk of neurological injury and proximal junctional kyphosis).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

1. Adolescent idiopathic scoliosis patients (10 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 >50 degrees;
3. Adolescent idiopathic scoliosis 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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2015
Enrollment:	33
Type:	Actual

Medical products/devices used

Generic name:	Minimal Invasive Deformity Correction (MID-C)/ApiFix System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-07-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL53495.029.15