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

Gepubliceerd: 15-07-2015 Laatst bijgewerkt: 13-12-2022

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

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

Samenvatting

ID

NL-OMON21786

Bron
NTR

Aandoening

Surgical treatment of adolescent idiopathic scoliosis (AIS).

Ondersteuning

Primaire sponsor: VU University Medical Center, Amsterdam, The Netherlands
Overige ondersteuning: VU University Medical Center, Dpt. of Orthopedic Surgery, Amsterdam, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2015
Aantal proefpersonen:	33
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-07-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5162
NTR-old	NTR5302
Ander register	Institutional Review Board, VU University Medical Center, Amsterdam, The Netherlands : 2015.223

Resultaten