Limited-efficacy testing of Spring Distraction System (SDS) and unilateral one-way rod (MID-C) for early onset scoliosis (UniPOWR study)

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON48743

Source
ToetsingOnline

Brief title
UniPOWR study

Condition

- Joint disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
Early Onset Idiopathic Scoliosis, spine curve

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ApiFix Ltd.,industrie

Intervention

Keyword: Distraction system, Early Onset Scoliosis, Growth friendly system, Unilateral

Outcome measures

Primary outcome

To assess the limited-efficacy and safety of SDS and MID-C EOS for treatment of progressive early onset scoliosis in ambulant patients. The limited- efficacy will be determined in terms of maintenance of correction and will be compared with a cohort of 17 patients previously treated by us with an MCGR system. Safety will be assessed in terms of treatment related SAEs and compared to the previous cohort and literature

Secondary outcome

1 To assess limited-efficacy in terms of length gain, Th1-Th12, T1-S1. The instrumented segment length will be measured on calibrated AP X-rays. Length gain will be compared to our previous cohort of MGCR patients and literature, including normal growth.

2 To compare the two systems with respect to:

a) limited-efficacy (maintenance of correction and lenght gain) and safety (SAEs)

b) Surgical parameters: surgery time, blood loss, length of hospital stay, recovery time, treatment related complications / reoperations

c) Bone density changes of the bypassed vertebrae, as assessed with DEXA post

op and 12 +/-3 months

d) Parent reported) QOL and performance with the EOSQ-24 questionnaire

e) Flexibility and 3D rotation of the spine based on echography

f) 3D development of the spine based on MRI

g) Patient overall appearance (shoulder balance, sagittal balance)

Study description

Background summary

Several innovative solutions have been developed to treat growing children with a progressive scoliosis. The SDS device was developed internally at the dpt. of orthopedics at UMC Utrecht, the Netherlands, the MID-C device was developed by ApiFix Ltd in Israel.

Study objective

The primary aim of this study is to investigate if these innovative surgical solutions are effective in maintaining curve reduction without repeat lengthening procedures and complications. Secondary aims are to investigate growth of the instrumented spine and to compare these devices.

Study design

A multicentre study with two prospective cohorts according an open label randomized clinical trial (RCT) design.

Intervention

Implantation with SDS or MID-C according to a randomized scheme

Study burden and risks

Both SDS and MID-C have been used in the clinical setting. For SDS, patients were included in the GRADS study at the UMC Utrecht and followed up prospectively. Until now 18 patients have been operated with a maximum FU of 10 months. MID-C has a longer track record for application in adolescents and is

CE marked for that purpose.

Burden: There is no extra burden with respect to the surgical procedure which is 2-4 hours and similar to other growing rod procedures. As part of this study, patients and parents will be asked to fill in questionnaires (2 per visit about 10 minutes), have 1 extra X-ray, 2 DEXA scans, 1 extra MRI and 3 echographies of the spine.

Risks: The biggest risk is that the implants will not maintain correction of the curve and/or not allow growth of the spine as intended. Another issue is that specific complications cannot be excluded. As compared to the MCGRs, the clinical data on growth is sparse. However, based on the early results of the GRADS study, curves are maintained and spinal growth is comparable to MCGR patients. The MID-C system is less invasive and less robust. This system is based on the AIS version, which has been successfully implanted for longer periods in adolescents and growth has been observed in young patients. If spinal growth is insufficient a small repeat operation may be needed for closed or open manual distraction. This is similar to the standard bi-annual procedure in conventional growing rods.

Benefits: The currently used MCGR and TGR have the disadvantage of the need for repeated lengthening procedures until skeletal maturity is reached. This is an extra burden for the patient although already much less when MCGR is used instead of TGR. However, the forced lengthenings are always non-physiological and may induce damage and/or spontaneous fusion of the spine. Also, each periodic lengthening causes a considerable stress on the construct which is related to both failure of the attachment to the spine (screw pull-out) and the instrumentation (rod fractures). In our own experience and supported by the literature, material failure rates of about 30% are reported for MCGR in 1-2 years. These problems can likely be diminished with the much more dynamic continuous self-growing systems.

Risk benefit analysis: The risk of complications compared to the conventional treatment strategies is minimal. This study can only be done in children with a growing spine as this is the essence of the treatment strategy.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1. Ambulant skeletally immature children, 6-12 yrs. of age, with open triradiate cartilages on X-ray
2. Scoliosis diagnosis prior to the age 10
3. Diagnosis of idiopathic or mild syndromic scoliosis (e.g. 22q11DS, Trisomy 21 or 9, Coffin-Siris)
4. Progressive scoliosis qualified for growth system surgery
5. One curve for treatment with an apex below Th5 and a proximal end vertebra below Th2
6. The primary curve must be between 35 and 75 degrees coronal Cobb angle
7. The primary curve must be non-rigid (i.e. the curve reduces on bending X-rays to <35 degrees or >30% of the curve)
8. Normal or hypokyphotic sagittal alignment (Th5 -Th12 < 50 degrees) on lateral X-rays

Exclusion criteria

1. Patients with an obvious neuromuscular disease
2. Patients that are severely mentally retarded
3. Patients with a scoliosis that extends to the pelvis or the cervicothoracic region
4. Patients with a main curve of more than 8 vertebra Cobb to Cobb
5. Patients with a skeletal dysplasia that effects growth (e.g. achondroplasia, SED)
6. Patients with a systemic disease which severely influences bone quality (e.g. osteogenesis imperfecta, metabolic diseases)

7. Patients with soft tissue weakness (e.g. Ehler Danlos, Marfan, Neurofibromatosis, Prader Willi)
8. Patients with an active systemic disease such as JIA, HIV or oncologic treatment
9. Patients with a previous surgical fusion of the spine
10. Known allergy to titanium
11. Patients weighing less than 11.4 kg or morbidly obese
12. Patients that are expected to be lost to FU due to e.g. immigration
13. Patient (or parents) that are expected to be non-compliant

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	28
Type:	Anticipated

Medical products/devices used

Generic name:	Minimal Invasive Deformity Correction system Early Onset Scoliosis (MID-C EOS)
Registration:	No

Ethics review

Approved WMO

Date:	26-03-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	21-06-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL63511.041.17
Other	Zodra de studie is goedgekeurd door de METC komt hier het NTC nummer