A safety and efficacy pilot study on the use of a continuous distraction spring in addition to growing rod surgery in children with congenital, neuromuscular or idiopathic spinal deformities.

Published: 29-06-2016
Last updated: 30-01-2025

To assess if the new operating technique is effective and safe.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56121

Source
ToetsingOnline

Brief title
GRADS

Condition

- Other condition

Synonym
scoliosis, Spinal growth deformities

Health condition

Scoliose

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Child, Growth, Spinal Deformity, Spine

Outcome measures

Primary outcome

(Serious) adverse events.

Secondary outcome

Length increase on standard spinal radiographs, difference in score on a validated scoliosis questionnaire: "revised Scoliosis Research Society 22-item questionnaire" and "Early Onset Scoliosis Questionnaire". Vertebral dimensions of the vertebrae measured on a (Bone)MRI-scan.

Study description

Background summary

Current treatment is placing a growth guidance system that has to be lengthened every 2 years in order for the spine to grow. By adding a distraction spring to the current systems, a continuous force can be delivered on the spine, mitigating the need for lengthening surgeries. The hypothesis is that this new surgical technique is effective and safe for use.

Study objective

To assess if the new operating technique is effective and safe.

Study design

A safety and efficacy pilot study

Intervention

Addition of a distraction spring to current growth guidance systems.

Study burden and risks

The benifit of avoiding the 2-yearly lengthening operations outweighs the risks of adding a spring to an existing growth guidance system. The force excerted from the distraction spring onto the growth guidance system is smaller than other forces on the growth guidance system during the operation. The risk is smal and the benefit can potentially be big. The (Bone)MRI-scan does not carry any radiation risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Children (2-11 years)

Inclusion criteria

Deformity Indicated for surgical treatment
Open triradiate cartilage
Normal skeletal development
Informed consent

Exclusion criteria

Closed triradiate cartilage
Systemic disease which severely influences bone quality
Disease that influences soft tissue quality
Abnormal skeletal development and growth
Patients that are expected to be lost to follow-up

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-09-2016
Enrollment:	160
Type:	Actual

Medical products/devices used

Generic name:	Spring Distraction System (SDS24)
Registration:	No

Ethics review

Approved WMO Date:	29-06-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	03-08-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-04-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-03-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-04-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-10-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-01-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-10-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-01-2025

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	NL55705.041.16