A Feasibility Study on the use of Percutaneous Instrumentation for less invasive surgery of Scoliosis Deformity in Children with Neuromuscular Disease.

Published: 23-12-2009
Last updated: 05-05-2024

To test the surgical feasibility of the less invasive percutaneous pedicle screw instrumentation system for the treatment of children with a so called "hypotonic" scoliosis. Additionally, postoperative pain reduction and a reduced hospital...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON33242

Source
ToetsingOnline

Brief title
LISCOS (Less Invasive Scoliosis Surgery)

Condition

- Bone disorders (excl congenital and fractures)
- Bone and joint therapeutic procedures

Synonym
acquired spine deformity, 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: Children, Neuromuscular Disease, Scoliosis, Spinal instrumentation

Outcome measures

Primary outcome

The technical feasibility to correct a neuromuscular scoliosis and to maintain

the correction using the experimental less invasive pecutaneous system.

Secondary outcome

The amount of blood loss, ICU stay (days), postoperative complications and the

amount of pain.

Study description

Background summary

Children with a neuromuscular disease (e.g. muscular dystrophy or cerebral palsy) or spina bifida will almost always develop a scoliosis deformity. Many times this deformity does not necessitate operative treatment. Sometimes there is a problem for the child to fit into his/her wheelchair due to the deformity of the spinal column (severity of the scoliosis). In these cases one could decide to perform an operative treatment.

Currently these children are treated by a posterior instrumentation with pedicle screws and rods on the backside of the spinal column for correction of the deformity. Sometimes, when the child is quite young and growth of the spinal column needs to be preserved as much as possible, metal lamina wires instead of pedicle screws are used over 2 metal rods allowing the child to grow and shift the wires over the rods for longitudinal growth. In both situations, the paraspinal muscles need to be stripped from the lamina on the back side of the vertebral column from neck to pelvis in order to reach a good exposure. This takes time and usually causes a blood loss of between 500 and 1000 cc of blood (which can partially be returned to the patient using cell saving

devices). Additionally, postoperative pain can be quite significant. All of these children will be admitted to the ICU for pain control and respiratory support. Usually they can be transferred to the clinical wards after 24 hours.

In the past years, new developments using less invasive surgery techniques have taken place in the treatment of adult spinal trauma patients. This percutaneous pedicle screw instrumentation system is currently applied on a regular basis in the UMCU for the treatment of spine fractures due to trauma or pathological causes such as primary tumors/metastases (the latter usually in addition to postoperative irradiation). Also the use of this thechnique in combination with less invasive anterieur spinal column surgery for deformities such as sponylolisthesis or degenerative scoliosis has been reported in the literature, making it a logical next step to apply this less invasive technique in children and adolescents with a scoliosis deformity. Recently, 12 adults with a degenerative scoliosis were treated with the less invasive percutaneous screw placement in combination with an anteriorly placed cage using a less invasive new approach (Anand et al., J Spin Disord Techn, 21(7), 459-467, okt 2008). The authors found a significant reduction in bloodloss. The follow-up time in this group is unfortunately quite short at this time making long term prognosis of this technique impossible to judge (also since the technique was combined with an anterior cage).

One obstacle could be the achievement of a true bony fusion (spondylodesis). Traditionally, in the open technique, bone graft is added to the posterior elements or to the anterior intervertebral space in order to achieve this fusion. Without this fusion, failure of the instrumentation could be the result. With the current experience in the UMCU on trauma patients, failure of the instrumentation was not observed until now. Perhaps a spontaneous fusion in these traumatically fractured vertebrae is the reason why this has not occured. Children, in scoliosis surgery, usually have no problem developing a bony fusion in comparison to adults. It is speculated that children will already develop a fusion due to surgery itself (the exposure procedure of the spine) because of their high numbers of stem cells that are triggered to make bone tissue due to the surgical procedure (stripping of the periosteum from the vertebral bone). Theoretically it is possible that children will also make this bone due to the percutaneous (less invasive) surgical procedure. In a feasibility study we would like to explore the possibility to correct scoliosis with the less invasive technique in a group of children with a disease state that causes a scoliosis deformity of the spine that can be easily corrected peroperatively and who have an activity level that puts less challenges on the new instrumentation system. Children with muscle dystrofy and/or cerebral paresis or a high spina bifida have a weak muscle tonus in their legs and paraspinal muscles making them easy to correct once they are under general anaesthesia. They usually do not need additional procedures such as the removal of the facet joints or flavum ligaments to mobilise the spine. These patient could potentially benefit the most from the new technique, especially since the trauma of surgery is reduced that may reduce the high rate of especially

pulmonary complications but also infections due to their lower level of resistance.

Study objective

To test the surgical feasibility of the less invasive percutaneous pedicle screw instrumentation system for the treatment of children with a so called "hypotonic" scoliosis. Additionally, postoperative pain reduction and a reduced hospital (ICU) stay is examined and considered part of the study objectives. The latter is however a secondary aim, which may be studied in a second more extensive study, since the feasibility of this new surgical technique first needs to be established.

Study design

The study is a therapeutic observational study.

Intervention

All children and adolescents will be treated with the percutaneous less invasive scoliosis correction. A group of 5 children will be studied first to observe any surgical adverse events or postoperative complications. When safety can be warranted, the second half of the study group will be treated.

Study burden and risks

The burden of the new surgical technique will not be bigger than with the current technique, potentially even less.

Potential risk factors:

Current risk factors:
- neurological deficit
- wound infections
- postoperative bleedings
- complaints caused by the profile of the fixation device used (screws, rods)

Potential new risk factors:
- loss of correction due to instrumentation failure (because no spondylodesis procedure is performed, just fixation of the spine)
- (more?) complaints caused by the profile of the fixation device used (screws, rods)

In case of loss of fixation due to instrumentation failure a secondary procedure may be needed using the standard open technique.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

age > 12 yrs < 18 yrs
neuromuscular disease or spina bifida with scoliosis deformity
scoliosis deformity that needs operative treatment

Exclusion criteria

age > or = 18 yrs
previous spine surgery
stiff scoliosis deformity with little chance for closed reduction (spastic children)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-09-2010
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	23-12-2009
Application type:	First submission
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	NL27477.041.09