Radiographic Analysis of the Sagittal Alignment and Balance of the Spine in Parents who have a Child with Adolescent Idiopathic Scoliosis

Published: 03-12-2007
Last updated: 10-05-2024

To investigate whether parents of children with adolescent idiopathic scoliosis have a significantly different neutral upright sagittal alignment compared to adult volunteers whose offspring does not have adolescent idiopathic scoliosis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON31519

Source
ToetsingOnline

Brief title
spinal and spinopelvic balance

Condition

- Musculoskeletal and connective tissue disorders congenital
- Bone disorders (excl congenital and fractures)

Synonym
adolescent scoliosis without a known cause

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: 3D reconstruction, adolescent idiopathic scoliosis, familial, spinopelvic balance

Outcome measures

Primary outcome

In general, we are interested in the total alignment and balance of the spine.

However, since the spine is a complex three-dimentional structure, there is not

just one parameter describing its balance or alignment. However, we are most

interested the spinal segment, which is backward tilted (the declive part), as

this is the part in which the dorsal shear forces are the biggest.

Subsequently, we suspect to find a difference between the parents of a child

with AIS and the control group. For that reason we are mainly interested in the

following parameters:

Declive length

Declive height

Declive offset

Spinal balance

T9 sagittal offset

For more detailed discription and illustrations, please see page 10-11 and

17-18 of the Research Protocol.

Secondary outcome

Other secundary study parameteres which describe the rest of the spinal

configuration are:

Inclination of vertebrae

Number of backward inclined vertebrae

Declive angle

Hip axis

Sacral slope

Pelvic tilt

Pelvic Incidence

Lumbar lordosis

Thoracic kyphosis

Ischio-Illiac axis

For more detailed discription and illustrations, please see page 10-11 and

17-18 of the Research Protocol.

Study description

Background summary

In spite of the many anatomical similarities of the spine between all vertebrates, true *idiopathic* scoliosis does not occur in primates other than man. A unique aspect of man compared to other vertebrates, quadruped as well as bipeds, is the way we ambulate in a fully upright posture, with extended hips and knees, placing the upper body*s centre of gravity consistently over the pelvis. All other vertebrates, even bipedal animals, have flexion contractures

of the hips and knees, and little or no pelvic or lumbar lordosis. This unique fully erect position of the human spine results in different loading of the vertebral column.

In all vertebrates, including humans, the spine is predominantly loaded by axial compression, which is mainly carried by the anterior column that consists of the vertebral bodies and intervertebral discs. However, due to the more erect human position, shear loads are differently orientated in the human spine. In a more horizontally (quadruped or bipedal) positioned spine shear loads are mainly ventrally directed, whereas in the more vertical human position, certain parts of the spine have been proven to be subjected to dorsally directed shear loads, as was shown in work by the investigators.

The anatomy of all spines, with broad discs and vertebral end plates, as well as the posterior location of the facet joints and the posterior pull of the predominantly posteriorly located muscles and spinal ligaments, is well designed to counteract both axial as well as ventrally directed shear loads. However, these anatomical stabilizing mechanisms are deficient in the case of dorsally directed shear loads, possibly leading to rotational instability.

Castelein et al. proposed two hypotheses regarding dorsal shear forces:
(1) Dorsal shear forces lead to rotational instability;
(2) Dorsal shear forces are the resultant vector of gravity and muscle activity, and act on certain parts of the spine depending on its orientation in space. These forces increase in magnitude with increasing backward tilt (declination) and with reduced thoracic kyphosis.
Indeed, a recent in vitro study on porcine and human spinal segments did show that dorsal shear loads lead to an impairment of rotational stability of the spine.

Although the specific cause of adolescent idiopathic scoliosis (AIS) has not been established, the role of genetic or hereditary factors in its development is widely accepted. Wynne-Davies performed a study that strongly supported a hereditary component. She examined 180 patients with AIS, and found in 25% that other members in the family were affected.8 A following population study found rates of affected first, second, and third-degree relatives of respectively 15.8%, 2.4%, and 1.4%. Furthermore, studies done on twins have shown a higher concordance rate for AIS in monozygotic twins than dizygotic twins, with a concordance rate of 73% versus 36% respectivably.
Despite these convincing arguments regarding the familial nature of AIS, the particular mode of inheritability remains unclear.

Our hypothesis is that certain spinal configurations predispose more than others for dorsal shear forces, and that these spinal configurations are inherited.
Therefore, we suspect to find a significantly different sagittal spinal alignment in the parents of children with AIS as compared to the normal

population.

Study objective

To investigate whether parents of children with adolescent idiopathic scoliosis have a significantly different neutral upright sagittal alignment compared to adult volunteers whose offspring does not have adolescent idiopathic scoliosis.

Study design

Retrospective case-controled study

Study burden and risks

The level of radiation is categorized as IIa (0,1-1,0 mSv) according to IRCP 62 (* Radiological Protection in Biomedical Research*). Which implies that the level of societal benefit should be intermediate. *To justify risk in category IIa, the benefit will probably be related to increases in knowledge leading to health benefit.*

Participating in this study is not a phycical or psychological burden. Furthermore, participating will only take approximately 30 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Both parents who have a child with adolescent idiopathic scoliosis (>= 30 degrees Cobbs angel) or whose child had a surgical correction

Exclusion criteria

- One parent not participating
- One of the parents aged >= 50 years
- One parent with a history of scoliosis, spinal trauma, spine surgery and no hip or back problems, except perhaps occasional low back pain, for at least six month before their participation.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-02-2008
Enrollment:	224
Type:	Actual

Ethics review

Approved WMO Date:	03-12-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-08-2008
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	NL18103.041.07