Prospective comparison in new challenging gait and balance tasks in female adolescents with idiopathic scoliosis before and following corrective spinal fusion

Published: 02-03-2011
Last updated: 03-05-2024

The aim of the present study is to use a more complete analysis of spinal motion (using a 3D multi-segment spine model) and to introduce challenging gait tasks which can optimally reveal the compensation strategies of the spine. Furthermore, static...

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

Summary

ID

NL-OMON34137

Source
ToetsingOnline

Brief title
Scoliosis_gait

Condition

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

Synonym
Adolescent Idiopathic scoliosis, spinal deformity

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: SMK Research BV

Intervention

Keyword: Gait analysis, Postural stability, Scoliosis, Surgical correction

Outcome measures

Primary outcome

In the static balance tasks the primary parameter is the vCOP and the RMS of the COP. In the challenging gait tasks the main parameter is the axial rotation of the different spinal segments in relation to each other and in relation to the pelvis.

Secondary outcome

General information like gender, age, length, weight and menarche will be collected. The Cobb angle will be determined on X-rays. Furthermore, walking speed, stride length and joint angles will be calculated. Functional scores will be related to the Cobb angle.

Study description

Background summary

Patients with disturbed trunk symmetry, such as patients with adolescent idiopathic scoliosis (AIS), have problems with stability control during standing and walking. Often these patients require spinal fusion surgery, which reduces the spinal mobility and affects the trunk biomechanics. So far, one lacks appropriate quantitative measures to assess the functional outcome of these interventions. At best, a simple gait analysis is performed using standard methods (lower limb kinematics and the global spinal kinematics such as acromion-pelvis (C7-S2) angle during simple level walking before and after surgery). Nevertheless, it is essential to study the (functional) changes

induced by the surgery, since these are apparently tolerated very well. In addition, one needs to learn how individual patients compensate for the fusion. It is most likely that adjacent vertebrae have to compensate for the loss in spinal mobility in AIS patients. Data of this type are clinically important since this allows us to study the biomechanically important effects of the number of fused vertebrae and the level of the fusion (thoracic or thoracolumbar). Moreover, this will help clinicians in predicting and avoiding additional problems that result from spinal fusion (e.g. adjacent segment degeneration, junctional kyphosis, *adding-on*).

Study objective

The aim of the present study is to use a more complete analysis of spinal motion (using a 3D multi-segment spine model) and to introduce challenging gait tasks which can optimally reveal the compensation strategies of the spine. Furthermore, static balance will be investigated.

Study design

Patients in this experimental study will be tested before and after surgery in demanding balance and gait tasks such as fast walking and walking uphill to test their functional potential and to highlight compensatory strategies. The measurements are non-invasive and also includes a questionnaire (SRS-22).

Study burden and risks

Patients will not be burden with excessive risks in case of participation, nor with benefits. The additional measurements in the gait laboratory will be performed, which will take some extra time. Patients are wearing a safety-belt during walking on the treadmill. Furthermore, no additional visits to the Sint Maartenskliniek will be necessary.
Participation of the patients is completely voluntary and patients have to sign the informed consent procedure. Patients are allowed to withdraw the study at any moment without reason. The privacy of the patients is protected with the following measures: case report forms are filed under code number; all involved investigators have professional responsibility not to compromise the confidentiality of patient information. This is also stated in the patient information. In reports, the patients will be presented anonymously.

Contacts

Public
Sint Maartenskliniek

Hengstdal 3
6522 JV Nijmegen
NL
Scientific
Sint Maartenskliniek

Hengstdal 3
6522 JV Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Adolescent Idiopathic Scoliosis
-age 12-18 years
-on waiting list for surgical correction

Exclusion criteria

-not being barred of any previous spinal surgery
-neurological or musculoskeletal disorders
-mental retardation

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2011
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	02-03-2011
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL35194.072.10

Study results

Date completed:	21-09-2013
Actual enrolment:	25