Posture Reproducibility and 3D Ultrasound Imaging of the Spine to Measure Scoliosis

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To obtain the reproducibility of the standing posture using with Der Wippe, a balancing device, with adjustable holder and acquire the 3D ultrasound of the spine of scoliotic patients

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

Summary

ID

NL-OMON32698

Source
ToetsingOnline

Brief title
Posture reproducibility & 3D ultrasound imaging for scolisis

Condition

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

Synonym
spinal curvature, ultrasonography

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 3D ultrasound, posture reproducibility, scoliosis

Outcome measures

Primary outcome

The main study parameter of the posture reproducibility study will be the

reproducibility of the posture in the different set-ups.

Secondary outcome

The main study parameters of the 3D ultrasound imaging and the MRI of the spine

will be vertebral features.

Study description

Background summary

Background :
Frequent monitoring of scoliosis progression is effective to define the severity and determine the best treatment.
X-ray is the gold standard to measure the spinal curvature in scoliosis, however, radiation exposure in X-ray limits the frequent monitoring of scoliosis to only twice a year.
Positional variability in spinal X-ray radiography could cause the wrong diagnosis and non-adequate or unnecessary treatment of scoliosis.
Vertebral arch surface reflection in 3D ultrasound imaging shows feasibility of utilizing this imaging system for monitoring scoliosis progression frequently in a safer way.
The prospective development of 3D ultrasound imaging for frequent monitoring of scoliosis requires a reproducible standing posture procedure.

Study objective

To obtain the reproducibility of the standing posture using with Der Wippe, a balancing device, with adjustable holder and acquire the 3D ultrasound of the spine of scoliotic patients

Study design

The study consists of two parts:
1) a posture reproducibility test applied for X-ray and ultrasound
2) a 3D ultrasound imaging of the spine taken in supine and standing positions.
Both parts are relevant for a future prospective cohort study.

Study burden and risks

This study has negligible risks and the burden is minimal. The posture reproducibility study for X-ray as well as ultrasound will only apply safe replica devices to mimic the real procedures. The postural movement will be measured using body markings derived from photographs taken with commercial digital cameras. The 3D ultrasound imaging of the spine will not impose any radiation exposure to the subjects and have no harmful side effects. X-ray images are not part of our study but obtained as part of standard medical procedures in these patients. For the MRI in healthy subjects, standard precautions are taken (MRI exclusion criteria) so that this part of the study also has minimal risks.
The posture reproducibility measurements will be performed on the same day as the patient has her regular appointment with the orthopedic surgeon, right before and after the consultation time. The 3D ultrasound imaging of the spine will be performed at a different day than the posture reproducibility test, but also in combination with an appointment with the orthopedic surgeon. Every part of the study will require 60 to 90 minutes per subject per session.
The physical and physiological discomfort associated with the study is very small. Participants in the study have no direct benefit from the study. In the long term, the results of this study may benefit the group of scoliotic patients because a more accurate standing posture may be determined and the amount of radiation involved in follow-up of scoliosis may be limited.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Idiopathic & congetinal scoliosis
Female / Girl
Age between 12 and 18 years old
Under treatment at scoliosis clinic in UMCG
Capable of standing up normally without any supporting devices
Range of Cobb angle : between 20° and 60 °

Exclusion criteria

Pregnancy
Accomplished spinal surgery
Back pain
Neurological disorder

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-02-2010
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL29540.042.09