Spine ultrasound imaging during different upright body positions to determine the most accurate representation of the neutral sagittal balance.

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To compare the effects of various upper extremity positions on the sagittal spinal alignment, to determine which position corresponds the most with the neutral position and to determine which position is the most reliable across repeated...

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

Summary

ID

NL-OMON46582

Source
ToetsingOnline

Brief title
Sagittal ultrasound

Condition

- Bone disorders (excl congenital and fractures)

Synonym
sagittal balance, Spine deformities

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: Sagittal profile, Spine, Ultrasound

Outcome measures

Primary outcome

The main study parameters are the thoracic and lumbar sagittal angles, as

measured by ultrasound imaging in the different positions.

Secondary outcome

NA

Study description

Background summary

The sagittal spinal alignment is an important aspect for the clinician to consider in the evaluation and treatment of patients with spinal pathologies and is becoming more important for the outcomes of surgical treatment. To capture the sagittal morphology, standing radiographs are the preferred standard. These radiographs are ideally performed, in a comfortable, functional, and naturally assumed posture, with the arms at the sides: the neutral position. However, in this position the arms inhibit adequate visualization of the spine on a lateral radiograph and therefore numerous positions have been developed in order to visualise the spine on the lateral radiograph, such as a standing position with the fingers on the cheeks. In these adjusted standing positions the position of the arms effects the alignment of the spine, as well as the reproducibility of measurements between subsequent radiographs. Previous authors compared the sagittal alignment in the different adjusted positions. Due to radiation exposure, these studies included only a restricted number of positions, or used external markers to compare the different positions. Ultrasound imaging enables us to compare the sagittal alignment of the neutral position with the adjusted positions, without radiation exposure. Therefore, in this study, 5 different standing positions will be compared by ultrasound imaging, to determine which position provides

the most *functional representation* of the neutral standing posture (with the arms on the side) and to determine which position is the most reliable across repeated measurements.

Study objective

To compare the effects of various upper extremity positions on the sagittal spinal alignment, to determine which position corresponds the most with the neutral position and to determine which position is the most reliable across repeated measurements.

Study design

Cross-sectional study

Study burden and risks

Ultrasound imaging is a widely used imaging technique in the regular care of patients and has proven to be a safe, non-radiating, fast and cheap method. The Scolioscan® (CE-marked) meets these characteristics too; the most important benefit of the Scolioscan® is the radiation-free examination in standing position. For this study, the volunteers will be examined by the ultrasound device, which takes approximately two minutes of scanning time per scan. If the most *functional representation* of the sagittal plane on a standing examination is known, this position could be used for all the imaging procedure, to make sure the different images are made in the same positions to avoid alignment differences due to the positioning. There are no noteworthy risks associated with participating in this study, and no invasive procedures or contrast administration will be performed.

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

Male or female healthy volunteer, 18 years or older, written informed consent.

Exclusion criteria

Any spine health issue, previous spinal surgery as well as disabilities to stand in one or more positions.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-03-2018
Enrollment:	30

Type:	Actual

Medical products/devices used

Generic name:	Ultrasound device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-02-2018
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	NL63909.041.17

Study results

Date completed:	21-02-2019
Results posted:	05-04-2019
Actual enrolment:	25

First publication

05-04-2019