Hyperkyphosis and the Cobb angle: is the Cobb angle affected by posture in older adults?

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To investigate: (1) the difference in degrees between a Cobb angle measured in supine position and standing position with standard instructions of the radiographer (main objective)(2) the correlation between the Cobb angle in both supine position...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON46029

Source
ToetsingOnline

Brief title
SKYFALL II

Condition

- Other condition
- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym
hyperkyphosis, increased curvature of the thoracic spine

Health condition

skeletspierstelsel- en bindweefselaandoeningen, subcategorie breuken

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Kyphosis, Measurement method, Older adults

Outcome measures

Primary outcome

The mean/standard deviation or median/interquartile range (IQR) of the

difference in degrees of the Cobb angle, measured in supine and standing

position.

Secondary outcome

-The correlation between three kyphosis measurement methods: the Cobb angle,

the blocks method and the OWD, presented as Intra Class Correlation

Coefficients and Bland Altman Plots.

-Interrater and intrarater variability of the Cobb angle

Study description

Background summary

Hyperkyphosis, an excessive curvature of the thoracic spine in the sagittal plane, is present in 20 to 40% in community-dwelling older adults and up to 55% in geriatric outpatients. Since multiple studies show an association between hyperkyphosis and negative health effects, like a decreased physical performance and a doubled fall risk, measuring hyperkyphosis is clinically relevant and should be done adequately.
The current gold standard, the Cobb angle, is the angle between the fourth and twelfth thoracic vertebra on a lateral radiograph. Some studies report a Cobb angle measured in supine position and some in standing position. As the kyphosis angle is influenced by many factors, such as the anatomy of the vertebra and back extensor muscle strength, we hypothesize that the posture of

the patient influences the Cobb angle. Furthermore, to be able to compare previous studies using different kyphosis measurement methods, we aim to investigate the correlation between the Cobb angle and two clinimetric kyphosis measurement methods: the blocks method and the occiput-to-wall distance.

Study objective

To investigate:
(1) the difference in degrees between a Cobb angle measured in supine position and standing position with standard instructions of the radiographer (main objective)
(2) the correlation between the Cobb angle in both supine position and standing position, the blocks method and the occiput-to-wall distance (OWD)
(3) the interrater and intrarater variability of the Cobb angle

Study design

Cross-sectional, single-center, observational cohort

Study burden and risks

The risks and burden of this study is considered to be low for participants. A lateral radiograph is standard care. Immediately after this radiograph, the additional radiograph will be made, and the two clinimetric kyphosis measurements will be performed. Altogether, this will take less than 10 minutes. No additional visits or questionnaires are needed.The radiation exposure of the additional radiograph of the chest is low: 0.02 mSV [1]. In comparison the radiation exposure in the Netherlands is 2.6 mSv per person yearly in the Netherlands.The lifetime attributable risk of cancer incidence for radiation exposure up to 10 mSV per year varies from 0.0002 to 0.0310, depending of age and gender of the patient.

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

*- geriatric outpatient referred to the geriatric outpatient clinic of the AMC Amsterdam
- aged 60 years or older
*- being able to stand and to lay down on a research table
*- enough language proficiency to understand the informed consent procedure and instructions during the kyphosis measurements

Exclusion criteria

- Parkinson*s disease or diseases associated with deformation of the spine in medical history
- Informed consent not provided

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-09-2018
Enrollment:	62
Type:	Actual

Ethics review

Approved WMO

Date:	04-09-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL66757.018.18