

Analysis of lumbar intervertebral motion during flexion and extension cinematographic recordings in asymptomatic male participants.

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Defining the lumbar spines* physiological motion by analyzing sequence of initiation of motion and sequence of maximum contribution in segmental translation and rotation of each vertebra L1, L2, L3, L4, L5 and S1 by using flexion and extension...

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

Summary

ID

NL-OMON46481

Source

ToetsingOnline

Brief title

Lumbar motion

Condition

- Other condition

Synonym

Lumbar motion, motion pattern of lumbar vertebrae

Health condition

fundamenteel bewegingsonderzoek

Research involving

Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Asymptomatic participants, extension cinematographic recordings, Flexion, Lumbar intervertebral motion, Segmental translation and rotation

Outcome measures

Primary outcome

Defining the lumbar spines* physiological motion by analyzing sequence of initiation of motion and sequence of segmental contribution in rotation of each vertebra L1, L2, L3, L4, L5 and S1 by using flexion and extension cinematographic recordings in asymptomatic male participants.

Secondary outcome

Exploring the possibility to analyze intervertebral horizontal and vertical translation of each vertebra L1, L2, L3, L4, L5 and S1 by using flexion and extension cinematographic recordings in asymptomatic male participants. If mean intra-class correlation coefficient is higher than 0.60, sequence of initiation of motion and sequence of segmental contribution of intervertebral horizontal and vertical translation will be analyzed.

Study description

Background summary

This study describes the physiological motion of the lumbar spine in asymptomatic male participants. Physiological motion of the lumbar spine is a

subject of interest for medical specialists and paramedics. Unfortunately, nobody knows exactly what physiological motion means. There are many studies about maximum range of motions of flexion and extension in the lumbar spine. Only a few studies describe segmental translation and rotation of individual segments during flexion and extension. Most of these studies describe results of pooled data instead of results of individual participants. They all describe sequence of initiation of movement, not sequence of maximum contribution of individual segments. Most of these studies plot cumulative rotation against specific time points or at specific lumbar ROMs* in graphs, which can lead to missing drastic changes in intervertebral translation and rotation between successive frames. Some of these studies only describe flexion not extension or limited flexion up to 40 degrees and limited extension up to 10 degrees.

Study objective

Defining the lumbar spines* physiological motion by analyzing sequence of initiation of motion and sequence of maximum contribution in segmental translation and rotation of each vertebra L1, L2, L3, L4, L5 and S1 by using flexion and extension cinematographic recordings in asymptomatic male participants. This information will be plotted with segmental translation of rotation against total range of motion of the lumbar spine for each individual participant. By analyzing each individual participant instead of pooled data, we will determine whether there is a specific motion pattern of individual segments during flexion and extension.

In the future we hope to compare these physiological kinematics to potential abnormal kinematics in patients suffering from lumbar spinal pathology, a common health care problem.

Study design

Fundamental research.

Study burden and risks

Participants will undergo two cinematographic recordings with an interval of two weeks. The radiation doses is calculated as 0.42 mSv per participant. This can be categorized in category IIa according to NCS guidelines. This means that a moderate risk is acceptable if the study provides health advantages for future patients. We strongly recommend that participants' partner will not get pregnant during this study or in the following year of the study because of the radiation dosage. The other recommendation for participants is not to participate in other studies using radiation dosage in the next following year.

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

1. Male
2. Age between 18 and 25 years old.
3. BMI under 25
4. Participants have to be able to perform flexion and extension over a full range of motion without complaints of pain.
5. Participants have no medical history of spinal problems based on anamneses and zero ODI-, and VAS-score.
6. Kellgrens* classification on cinematographic recordings is zero or one.
7. Informed consent has been signed.
8. Ability to read and understand Dutch.

Exclusion criteria

1. Medical history of visiting general practitioners, allied health professionals or specialists for spinal problems.
2. Former spine surgery.
3. Radiographs of abdomen, pelvis, hips, lumbar spine or sacral spine in last year.
4. Degenerative abnormalities of the lumbar spine.
5. Active spinal infection.
6. Immature bone.
7. Lumbar tumor processes.
8. Former lumbar radiotherapy.
9. Congenital lumbar spine abnormalities, for example spina bifida.
10. Planning pregnancy for the coming year.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 04-02-2019

Enrollment: 11

Type: Actual

Ethics review

Approved WMO

Date: 24-09-2018

Application type: First submission

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

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	NL63033.096.18