

STEADY; sustained technology for the evaluation of lumbar atrophy and dysfunction*

Published: 20-10-2016

Last updated: 14-04-2024

Using technology for improving diagnostics of non-specific lower back pain by physiotherapists

Ethical review	Not approved
Status	Will not start
Health condition type	Muscle disorders
Study type	Observational non invasive

Summary

ID

NL-OMON43299

Source

ToetsingOnline

Brief title

STEADY;

Condition

- Muscle disorders

Synonym

non-specific lower back pain

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: - lumbar atrophy, - multifidus, - technology

Outcome measures

Primary outcome

The primary study parameters are the amount of EMG, with parameters relative rEMG, amplitude (mV), frequency amount (Fmed) in Hz. Range of motion of the trunk by using 3D kinematics and cross-sections and fatty degeneration of the multifidus by using ultrasound.

Secondary outcome

Personal characteristics.

Study description

Background summary

Non-specific lower back pain is a pain syndrome, however the exact cause is not known. Probably there are several factors that contribute to this pain syndrome. The last several years, people are interested to divide non-specific lower back pain patients in different subgroups. Because these different subgroups need probably different specific treatments. In physiotherapy treatment the most attention focused on disbalance between back and belly muscles. This project will focus on validation of technology to improve the diagnosis of non-specific lower back pain by physiotherapists. Ultrasound, surface electromyography and 3D accelerometry will be validated to improve distinguishing of subgroups of non-specific lower back pain patients by physiotherapists.

Study objective

Using technology for improving diagnostics of non-specific lower back pain by physiotherapists

Study design

cross sectional study design

Study burden and risks

The burden of the subjects are very limited. Subjects will be measured once at one of the diagnostic centers. This will be taken a maximum of one hour. All the technology measurements are used as care as usual at physiotherapist centers, and there will not be measured invasive. There will be no risks associated with participation.

The advanced of participating in this study for the subjects is, they will contribute to create more knowledge about to diagnostic non-specific lower back pain patients in the physiotherapy. The subjects will get traveling expenses and a cheque of 15 euros for participation in this study.

Contacts

Public

Universitair Medisch Centrum Groningen

hanzeplein 1
 groningen 9713 EZ
 NL

Scientific

Universitair Medisch Centrum Groningen

hanzeplein 1
 groningen 9713 EZ
 NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients

- * Between 18 and 65 years old
- * Acute (<6 weeks), subacute (6-12 weeks), chronic non-specific lower back pain (> 12 weeks)
- * Score > 30% points at the Oswestry Disability Index (ODI)
- * Signed the informed consent form

Healthy subjects

- * Between 18 and 65 years old
- * Signed the informed consent form

Exclusion criteria

Patients

- * Presence of red flags and lumbar/sacral radicular syndrome
 - * Previous back surgery
 - * Pregnancy
 - * Psychiatric diagnosis
 - * Insufficient knowledge of the Dutch language
- ### Healthy subjects
- * non-specific lower back pain
 - * Presence of red flags and lumbar/sacral radicular syndrome
 - * Pregnancy
 - * Previous back surgery
 - * Psychiatric diagnosis
 - * Insufficient knowledge of the Dutch language
 - * Body mass index > 30

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	200
Type:	Anticipated

Ethics review

Not approved	
Date:	20-10-2016
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	NL59241.042.16