Quantitative diagnosis of impaired spinal control (Qdisc): assessment of neuromuscular trunk motor control in chronic a-specific low back pain patients.

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

Summary

ID

NL-OMON39991

Source
ToetsingOnline

Brief title
Trunk control in low back pain patients.

Condition

- Other condition
- Musculoskeletal and connective tissue disorders NEC

Synonym
Chronic a-specific Low Back Pain, Low back pain

Health condition

Chronische a-specifieke lage rugpijn

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting voor de Technische Wetenschappen (STW)

Intervention

Keyword: Back pain, Trunk control

Outcome measures

Primary outcome

The main parameter is neuromuscular motor control, which can be described as trunk stiffness, reflexes in response to external force perturbations and trunk muscle recruitment.

Secondary outcome

Anthropometrics: body length and weight. Pain level, pain perception and kinesophobia will be measured with questionnaires. Also pain diaries will be filled every day for one week prior the measurements to measure pain level. Sensitisation for pain, the ability to inhibit pain and trunk coordination will be tested.

Study description

Background summary

Low-back pain is one of the most costly health problems in the industrialized world. Impairments of neuromuscular control may play a key role in LBP. Hence, identification of neuromuscular control of the trunk is needed to obtain insight in the adaptive or maladaptive nature of changes in control and to provide a window on the effects of pain, sensitization for pain and

proprioception.

Study objective

The primary goal is to investigate the ability of an integrated closed-loop identification system to differentiate between chronic a-specific LBP patients and healthy controls in terms of their neuromuscular trunk control. Also the influence of pain, sensitisation for pain and proprioception on the neuromuscular motor control will be investigated. Test-retest measurements will be performed to establish the smallest detectable differences of the estimated parameters. And the short-terms and long-term responsiveness of the integrated closed-loop identification system will be investigated.

Study design

The neuromuscular motor control of 24 patients from the VU medical centre, 24 patients from Rehabilitation centres Reade and Heliomare, and 25 healthy controls will be measured at baseline. A test-retest will be performed by measuring 24 patients < 2 weeks after baseline and the healthy subjects will be measured < 3 days after baseline. A responsiveness study will be performed by measuring the patients from the VUmc one week before, <1 week after and two months after they receive a nerve block (not provided as part of the research). The patients from Rehabilitation centres Reade and Heliomare will be measured at the start of a rehabilitation program, 2 months and 4 months after.

Study burden and risks

The risks for the subjects are minimal because the applied perturbations to will have a maximum of 100 N, which is lower than forces applied in other studies. The measurements (included explanation and preparation) will take 2,5-3 hours. Filling in questionnaires before each measurement which will take 30-45 minutes. The pain diaries will have to be filled in by the patients every day for one week before measurement and this takes 5-10 minutes per day. With this research we hope to gain more insight in the impaired motor control of LBP patients. Proposed system for identification of trunk muscle control will allow objective and quantitative monitoring of impairments of neuromuscular control of the trunk in LBP patients and quantification of the interaction with pain, sensitisation for pain and proprioception. This will shed light on the importance of the main prognostic factors for an individual patient and will support the implementation of more targeted treatment in chronic LBP patients and reduce the high number of non-responders to treatment.

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

Patients have to:
- be between the age of 18 and 70 years
- have a-specific LBPor LBP followed by back surgery for at least 6 weeks, as diagnosed by the patient*s general practioner or
physical therapist. Or, if no prior diagnosis has been made, after screening by an independent physical therapist or orthopaedic surgeon
- be able to understand and speak Dutch;Healthy controls have to:
- be age matched with the LBP patients
- be able to understand and speak Dutch

Exclusion criteria

Patients must not have:
- Radicular pain caused by lumbar nerve root compression or a hernia nuclei pulposi
- Other specifically diagnosed musculoskeletal disorders or any neuroanatomical disorders which might influence motor control of the low back
- any neurological disorders that interfere with trunk posture (e.g. Cerebro Vasculair Accident, Multiple Sclerosis or Parkinson's disease)
- any conditions that render the patient too unfit to be tested (such as pulmonary and/or cardiac disorders)
- any conditions that render the patient unable to understand or adhere to the research (such as cognitive, visual and/or language problems, that render the patient unfit to fill-in the questionnaires)
- Psychopathology

Healthy controls may not have:
- had low back pain longer than 2 weeks
- had low back pain within at least a month before the baseline measurement
- any conditions that render the subject unable to understand or adhere to the research (such as cognitive, visual and/or language problems, that render the subject unfit to fill-in the questionnaires)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-10-2013
Enrollment:	73
Type:	Actual

Ethics review

Approved WMO Date:	03-04-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-01-2014
Application type:	Amendment
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	NL42649.029.13