

Muscle activation patterns in chronic low back pain patients and pain free subjects.

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The primary objective of this study is to gain more insight in the muscle activation patterns of low back muscles during daily living in chronic low back patients and in pain free subjects.

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

Summary

ID

NL-OMON30842

Source

ToetsingOnline

Brief title

Muscle activation patterns in CLBP patients and pain free subjects.

Condition

- Other condition

Synonym

chronic low back pain

Health condition

chronische lage rugpijn

Research involving

Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh

Source(s) of monetary or material Support: Ministerie van VWS

Intervention

Keyword: Chronic Low Back Pain, muscle activity patterns, SEMG, Surface electromyography

Outcome measures

Primary outcome

The main study parameter is muscle activity pattern in daily life, expressed as two sided low back SEMG, measured using a belt with SEMG electrodes.

Secondary outcome

To obtain information of the composition of the study groups several questionnaires are used. Following aspects are determined:

For both groups: Demographics, self-perceived activity level.

For the patient group: Fear of movement, coping strategies, disability level, pain intensity.

Study description

Background summary

Despite extensive research, the etiology of chronic low back pain (CLBP) remains largely unknown. Musculoskeletal and biomechanical factors in the etiology and maintenance of CLBP have been investigated using surface electromyography (SEMG). All reported SEMG studies are based on laboratory experiments. These studies have proven that the muscle activity in CLBP patients is different as compared to healthy subjects. However, muscle activation characteristics during laboratory tests might be different from those in a daily life setting. The long term muscle activation pattern may provide information which cannot be obtained in laboratory experiments. To gain

insight in the long term muscle activation patterns, it is necessary to measure the muscle activation during daily activities. In the present explorative study the low back muscle activity patterns during daily activities will be determined in CLBP patients and in pain free subjects. The results of this study may provide useful information for further research investigating abnormal muscle activity patterns in CLBP and for research designing treatment methods for CLBP patients. For the purpose of this study a belt with integrated electrodes has been developed enabling ambulant registration of low back muscle activity.

Study objective

The primary objective of this study is to gain more insight in the muscle activation patterns of low back muscles during daily living in chronic low back patients and in pain free subjects.

Study design

A cross-sectional study case-control study will be performed to investigate the research questions.

Study burden and risks

The participants are not exposed to any risks. The laboratory exercises are safe and non intensive. The long term measurements are safe but discomfort may be caused by the belt and electrodes. The long period of skin contact of the electrodes and the conductance gel may cause some skin irritation. Due to tension of the belt around the low back and abdomen, this may somewhat give a corset-like feeling. The complaints disappear usually within a few minutes after removal of the belt.

The subjects are required to fill out questionnaires during the visit at RRD. The number of questions for patients and pain free subjects is 117 and 19, respectively.

All questionnaires are validated and modifications may result in that the given answers are unusable. The relative large amount of questions in the questionnaire for patients are required to obtain information about the nature of the back complaints. This information is essential for the scope of this study.

During the long term measurements the subjects are required to indicate their activities in a diary. The subjects are drawn attention to the possibility to skip parts of the diary for privacy reasons.

Contacts

Public

Revalidatiecentrum Het Roessingh

Roessinghsbleekweg 33B

7500 AH Enschede

Nederland

Scientific

Revalidatiecentrum Het Roessingh

Roessinghsbleekweg 33B

7500 AH Enschede

Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients:

-aged between 18 and 65 years;

-primary complaint is non-specific CLBP prolonging for longer than three months with no further pathology;

-availability of a partner or friend to assist with electrode belt positioning.;

Pain free subjects:

-aged between 18 and 65 years;

-No history of low back pain (requiring medical consultation) in the past 12 months;

-availability of a partner or friend to assist with electrode belt positioning.

Exclusion criteria

Patients:

- wheelchair-bound patients
 - patients with specific causes of CLBP;
 - patients who had surgery in the last 6 months;
 - patients with terminal or progressive diseases;
 - patients with insufficient knowledge of Dutch language;
 - Patients from non western cultures.
- a Body Mass Index (BMI) larger than 30 or less than 18.;
- Pain free subjects:
- The subject is employed at Roessingh Research and Development;
 - subjects with insufficient knowledge of Dutch language;
 - persons from non-western cultures;
 - a Body Mass Index (BMI) larger than 30 or less than 18.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2007
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO	
Date:	05-07-2007
Application type:	First submission

Review commission:

METC Twente (Enschede)

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	NL17723.080.07