MRI study of dynamic isolated lumbar extensor resistance training effect on multifidus muscle cross sectional area and fat infiltrations in patients with non-specific low back pain - a pilot study.

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

Summary

ID

NL-OMON36072

Source
ToetsingOnline

Brief title
Multifidus-studie

Condition

- Other condition
- Muscle disorders

Synonym
chronic low back pain, lumbago

Health condition

aspecifieke lagerugpijn

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MRI, Multifidus, non-specifiic low back pain

Outcome measures

Primary outcome

The lumbal multifidus muscle may be imaged by ultrasound, CT and MRI. Ultrasound is only suitable for superficial muscles and the resolution is low, which will lead to inferior tissue discrimination. CT and MRI have a highter resolution and therefore good tissue discrimination. Given the radiation exposure of CT, MRI is the most appriorate method for this study. The measurements will be performed by manually drawing the circumference of the muscle. Software will calculate the cross sectional area. Fat infiltration will be divided according to standard criteria:

- Normal/mild (fat infiltration < 10% of the cross sectional area)
- Moderate (fat infiltration > 10% and < 50% of the cross sectional area)
- Severe (fat infiltration > 50% of the cross sectional area)

The functional cross-sectional area (FCSA) of the muscle will be calculated to quantify the condition of the muscle. The FCSA is the cross sectional area of the muscle isolated from fat.

Secondary outcome

To quantify the level of functional (ADL) limitations caused by low back pain,

all participants will fill in validated questionaire at the time they undergo

the MRI scans: the Roland-Morris Disability Questionnaire (RDQ) and the Patiënt

Specifieke Klachten (PSK). Fysiotherapie MTG uses these questionaire for all

patients.

Study description

Background summary

Non-specific low back pain is very common; 60 to 80 percent of the Western population will experience an episode during their lifetime. The lumbal multifidus muscle plays a role in non-specific low back pain. 80% of the people with non-specific low back pain have lumbal multifidus muscle atrophy. Recently research has shown low back pain is treated effectively with reactivation and strengthening of the small muscles of the back. After this therapy long term stabilization of the vertebral column is improved. OriGene developed an isolated low back training with positive clinical results in patients with non-specific low back pain. To understand the effects of this therapy, it is relevant to study the effect of this therapy on the lumbal multifidus muscle.

Study objective

The objective of this prospective study is to answer the question: "Leads isolated dynamic resistance training of the lumbal extensor muscles to decreased multifidus atrophy and will MRI show an increasing multifidus cross sectional area and decrease of multifidus fat infiltration?"
Secundary question: "Is there a relation between decreasing multifidus atrophy and self experienced functional low back pain?"
This is a pilotstudy, if this study shows results it will be expanded to a study with a larger population.

Study design

At the start of the study patients will undergo an MRI scan, in which the cross sectional area and fatinfiltration percentages of the lumbal multifidus muscle will be measured in the axial plane at three disci levels: L3-L4, L4-L5 and

L5-S1. Patients will also fill in validated questionnaire concerning functional (ADL-) limitations caused by low back pain. After this 20 minutes MRI scan the patients will undergo once a week an isolated dynamic resistance training during ten weeks, in which the lumbal extensor muscles will be trained. They will not undergo any other therapy. After the ten weeks of training, the interval of training will depent on the patients' need.

Thirteen respectively twentysix weeks after the baseline MRI a second respectively thirt MRI scan will be made, in which the cross sectional area and fatinfiltration of the lumbal multifidus muscle will be measured at the same locations. Again patients will fill in validated questionnaire about low back pain.

This study will demonstrate the effect of isolated dynamic resistance therapy on cross sectional area and fatinfiltration of the lumbal multifidus muscle. This effect will be compared with the answers of the questionaire.

This study is a pilot-study. As control-group five of the twinty patients will undergo an extra MRI, four weeks prior to the baseline MRI. During these four weeks patients will undergo no therapy.

Intervention

The participants will undergo once a week an isolated dynamic resistance training during ten weeks, in which the lumbal multifidus muscle will be trained. They will undergo no other back muscle therapy and no medicine restrictions are imposed. After ten weeks the interval of training will depend on the participant's needs. Except for the MRI scans their treatment equals the regular treatment.

Study burden and risks

Participants will undergo dynamic isolated lumbal extensor resistance training and three or four MRI scans. The trainig will take place under direct supervision of a physiotherapist. The MRI scans have no radiation exposure and no contrast will be administered. Before a participants will be included in the study, he/she will be asked whether he/she has metal in his/her body (e.g. pacemaker of metal splinter in the eye) or is claustrophobic.

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

- Sex: man
- Age: 30 years or older
- Symptoms: non-specific low back pain since 12 week or longer .

Exclusion criteria

- Sex: woman
- Age: younger than 30 years
- History of surgical lumbal intervention, myopathy, muscledystrophia, spinal deformaty, idiopathic scoliosis, vertebral fractures, congenital malformations, severe hernia in need of a surgical intervention, spondylolysis, osteoporosis, vertebral metastasis and morbus Bechterew. Physical effort leads to extra exclusion criteria: angina pectoris, untreatable hypertension, untreatable diabetes mellitus, epilepsia, active rheumatic disease, severe neurologic degenerative diseases like multiple sclerosis and severe coagulation disorders.
- MRI contra-indications: claustrophobia, metal in the body (e.g. pacemaker, splinter in the eye).

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-05-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	16-05-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL35526.100.11