The effect of ultrasound as a treatment for long lasting low back pain.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23904

Source
NTR

Health condition

chronic low back pain; rugklachten

Sponsors and support

Primary sponsor: Tehran University of Medical Sciences, Iran
Source(s) of monetary or material Support: Self-funded; Tehran University of Medical Sciences, Iran

Intervention

Outcome measures

Primary outcome

1. Functional disability due to low back pain, measured by the Roland Morris Disability Questionnaire;

2. Pain intensity measured by the visual analog scale (VAS);

3. Functional rating index (FRI).

Secondary outcome

1. Paravertebral muscle fatigue during a Beiring-Sorensen test;

2. Lumbar flexion and extension range of motion using modified modified Schober method.

Study description

Background summary

Chronic non-specific low-back pain (NSLBP) is one of the most common and expensive musculoskeletal disorders in industrialized countries. One of the most widely used modalities in the field of physiotherapy for treating LBP is therapeutic ultrasound. Despite its common use, there is still inconclusive evidence to support its effectiveness in this group of patients. This trial will evaluate the effectiveness of continuous ultrasound in addition to exercise therapy in patients with chronic NSLBP.
A total of 50 patients, between the ages 18 and 65 years old who have had NSLBP for more than three months will be recruited from university hospitals. Participants will be randomized to receive continuous ultrasound plus exercise therapy or placebo ultrasound plus exercise therapy. These groups will be treated for 10 sessions during a period of 4 weeks. Primary outcome measures will be functional disability and pain intensity. Lumbar flexion and extension range of motion (ROM) as well as changes in electromyography muscle fatigue indices during the Sorensen test will be measured as secondary outcomes. All outcome measures will be measured at baseline, after completion of the treatment sessions, and after three months.

The results of this trial will help to provide some evidence regarding the use of continuous ultrasound in chronic NSLBP patients. This should lead to a more evidence-based approach to clinical decision making regarding the use of ultrasound for NSLBP.

Study objective

Therapeutic ultrasound will be more effective than placebo ultrasound at reducing pain and improving function in chronic low back pain patients.

Study design

Baseline (randomization), 4 weeks (post-treatment), 3 months.

Intervention

Continuous therapeutic ultrasound therapy plus semi-supervised exercise program versus placebo ultrasound plus semi-supervised exercise program.

Subjects in each group will receive 10 sessions of treatment, each around 20 minutes, during a period of 4 weeks.

Semi-supervised exercies program involves a series of exercies taught to the patient, who will be expected to continue them at home. When patients present for the experimental treatment, their exercies will be checked and progressed. Exercises involve lower limb stretching and abdominal/trunk muscle strengthening.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with NSLBP who have pain for more than 3 months will be eligible.

Exclusion criteria

Patients with underling systematic or visceral disease and specific conditions such as neoplasm, fractures, spondylolysthesis, spondylolysis, spinal stenosis, ankylosing spondylitis, previous low back surgery, and pregnancy will be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2010
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-03-2010
Application type:	First submission

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
NTR-new	NL2127

Register	ID
NTR-old	NTR2251
Other	METC Tehran University of Medical Sciences : 01032010
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A