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

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23904

Bron
NTR

Aandoening

chronic low back pain; rugklachten

Ondersteuning

Primaire sponsor: Tehran University of Medical Sciences, Iran
Overige ondersteuning: Self-funded; Tehran University of Medical Sciences, Iran

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2010
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-03-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2127
NTR-old	NTR2251
Ander register	METC Tehran University of Medical Sciences : 01032010
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A