Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

Comparison of stabilization exercise and general exercise on enhancing back stability in non-specific chronic low back pain patients using a biomechanical model(EMG-based)

Protocol summary

Summary

Objectives: There is a controversy about core stability exercise(CSE) in the literature. Some believe that this type of exercise has no special effect on LBP and only has some useful physiologic effects like other general exercises. Researches which have assessed this exercise had pain, disability, health related quality of life and ... as outcome measures and no study was found related to back stability. As the aim of CSE is to enhance back stability by improving local muscle contraction, assessing back stability in CSE is important. We decided to use a EMG-based biomechanical model to assess back stability. Design: Randomized, Phase 2 clinical trial Setting and conduct: Low back pain patient referred to physiotherapy department of Rasool hospital, Tehran, Iran were conducted in this study Participants including major eligibility criteria: Inclusion Criteria: Non-specific low back pain and pain VAS of 3-6 and exclusion criteria :any pathology or anomaly in lower extremity or spine Intervention: Subjects are randomly allocated in core stability and general exercise groups. Both exercises groups protocols are based on the study conducted by Koumantakis et al in 2005 (Trunk Muscle Stabilization Training Plus General Exercise Versus General Exercise Only). Interventions and training will continue for 6 weeks (tree session each week, total 16 sessions). Main outcome measures: By taking EMG from trunk muscles(Rectus, external and internal oblique, longisimus and iliocostalis) and using biomechanical equations we can estimate muscles force and so muscles stiffness. Stability index which is obtained in this way will be our main outcome measure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111098035N1**
Registration date: **2013-01-21, 1391/11/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-01-21, 1391/11/02

Registrant information

Name

MohammadBagher Shamsi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of medical sciences

Expected recruitment start date

2012-07-14, 1391/04/24

Expected recruitment end date

2013-02-12, 1391/11/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of stabilization exercise and general exercise on enhancing back stability in non-specific chronic low back pain patients using a biomechanical model(EMG-based)

Public title
Comparison of two types of exercise on enhancing back stability in non-specific chronic low back pain patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Non-specific LBP for more than 3 months; age 18-60 years; pain 3-6 in VAS scale.
Exclusion Criteria: Any pathology or anomaly in lower extremity or spine (like malignancy; inflammatory diseases; sever osteoporosis and bone and joint diseases); history of disc herniation or surgery in the spine.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commitee of Tehran University of medical Sciences
Street address
Keshavarz Bulevard, corner of Ghods Street
City
Tehran
Postal code
Approval date
2012-07-11, 1391/04/21
Ethics committee reference number
130/670/1/د

Health conditions studied

1

Description of health condition studied
Low Back Pain
ICD-10 code
M54.9
ICD-10 code description
Dorsalgia, unspecified

Primary outcomes

1

Description
Lumbar Stability index using a biomechanical model
Timepoint
Before and after the intervention
Method of measurement
Electromyografic signals of 5 abdominal and back muscles are taken and in a model they are converted to stability index.

Secondary outcomes

1

Description
Oswestry disability index
Timepoint
Before and after intervention
Method of measurement
Questionnaire

2

Description
Core stability
Timepoint
Before and after intervention
Method of measurement
With core endurance tests (trunk flexion and extension, and bilateral side bridge) and dynamic functional tests (Dip, single leg squat and runner pose)

3

Description
Abdominal muscle thickness (rectus, obliques and transverse)
Timepoint
Before and after intervention
Method of measurement
With ultrasonographic imaging

Intervention groups

1

Description
16 session of core stabilization exercise (3 each week)

based on study of Koumantakis

Category

Rehabilitation

2

Description

16 session of general exercise (3 each week) based on study of Koumantakis

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Department, Rasool Akram Hospital

Full name of responsible person

MohammadBagher Shamsi

Street address

Niayesh Street, Satarkhan Street

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of medical sciences

Full name of responsible person

Dr Akbar Fotoohi

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6th floor, University central office, corner of Ghods street, Keshavarz bulevard

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran University of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran university of medical sciences

Full name of responsible person

MohammadBagher Shamsi

Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty