Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of lumbosacral orthosis on thickness/cross-sectional area of trunk muscle stabilizers using ultrasound imaging in patients with low back pain

Protocol summary

Summary

Objective: To evaluate the effect of non-extensible lumbosacral orthosis on thickness/cross sectional area of trunk stabilizers muscles using ultrasound imaging in patients with non-specific chronic low back pain, Study design: A single-blinded randomized controlled trial, Population and sample size: Thirty four participants (20-55 years old) with chronic non-specific low back pain, for at least for 12 months, serious enough to require medical attention or absence from work. Intervention: participants will be randomized in to experimental or control group, both groups will receive 8 treatment sessions for a period of 4 weeks (twice a week). Common physiotherapy modalities will comprise of moist heat, ultrasound, TENS, posture and activity education, and flexibility exercises. Patients in the experimental group will be prescribed a non-extensible lumbosacral orthosis over the whole duration of the trial, and during the whole day, with the exception of bedroom and bathroom activities. Outcome measures: The primary outcomes include thickness of transverses abdominis and external oblique, and cross sectional area of lumbar multifidus that will be measured by ultrasound . Secondary outcomes are pain intensity, Oswestry Disability Index.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015083123836N1**
Registration date: **2015-11-02, 1394/08/11**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-11-02, 1394/08/11

Registrant information

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Fatemeh Azadinia

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-11-06, 1394/08/15

Expected recruitment end date

2016-05-17, 1395/02/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of lumbosacral orthosis on thickness/cross-sectional area of trunk muscle stabilizers using ultrasound imaging in patients with low back pain

Public title

Effect of orthosis on low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

The subjects are included in LBP group if they meet the

following criteria: age between 20 and 55 years, experience of back pain for at least for 12 months serious enough to require medical attention or absence from work, at least 1 episode of LBP in the last 6 month or pain with semicontinuous nature, no history of red flags, no history of core-strengthening exercise or physiotherapy and wearing orthosis during the past 6 month, no history of muscle relaxant medication, 3≤ VAS ≥7, ODI > 6. Individuals with a history of vestibular disorder, muscular dystrophy, neurological or sensory disorders, cardiac and respiratory disease, previous spinal surgery, serious neck problems, spinal structural deformity (kyphosis or scoliosis) , uncorrected vision impairment, vestibular disorder, pregnancy, diabetes, unequal length > 1 cm, osteoarthritis of hip and knee, BMI > 30, will be excluded. Also the subjects will be excluded if they have a hobby or job that requires extension of back or abdominal muscle training, a condition that requires prescription of muscle relax agents, or current use of analgesic medications other than acetaminophen (especially NSAD)

Age
From **20 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iran University of Medical Sciences

Street address
Hemmat Highway

City
Tehran

Postal code

Approval date
2015-08-30, 1394/06/08

Ethics committee reference number
IR.IUMS.rec.1394.26454

Health conditions studied

1

Description of health condition studied
Low back pain

ICD-10 code
M54.5

ICD-10 code description
Loin pain Low back strain Lumbago NOS

Primary outcomes

1

Description
Thickness of Transversus abdominis and External oblique muscle

Timepoint
before & after 4 weeks intervention

Method of measurement
Ultrasound measurements, milimeter

2

Description
Cross-sectional area of multifidus

Timepoint
Before & after 4 weeks intervention

Method of measurement
Ultrasound measurements

Secondary outcomes

1

Description
Pain intensity

Timepoint
Before and after 4 weeks intervention

Method of measurement
Visual analogue scale

2

Description
Disability

Timepoint
Before & after 4 weeks intervention

Method of measurement
Oswestry Disability Index

Intervention groups

1

Description
Patients in the experimental group will be prescribed a non-extensible lumbosacral orthosis over the whole

duration of the trial, and during the whole day, with the exception of bedroom and bathroom activities. Moreover they will receive 8 physical treatment sessions for a period of 4 weeks (twice a week). Common physiotherapy modalities will comprise of moist heat, ultrasound, TENS, posture and activity education, and flexibility exercises.

Category

Treatment - Other

2

Description

Patients in the control group will receive 8 physical treatment sessions for a period of 4 weeks (twice a week). Common physiotherapy modalities will comprise of moist heat, ultrasound, TENS, posture and activity education, and flexibility exercises.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation school, Iran University of Medical Sciences

Full name of responsible person

Fatemeh Azadinia

Street address

School of Rehabilitation Sciences, Nezam Alley, Shahnazari St. Madar Sq. Mirdamad Blv.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Ali Javad Mossavi

Street address

Hemmat Highway, Iran University of medical Sciences

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Name of organization / entity

School of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person

Fatemeh Azadinia

Position

Ph.D candidate

Other areas of specialty/work

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Person responsible for scientific inquiries

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PhD. in physical therapy

Other areas of specialty/work

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Person responsible for updating data

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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