Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the Effects of Standard Rehabilitation Protocol and Standard Rehabilitation Protocol in Combination with Exercise Therapy, on Functional Disability and Pain in Subjects Affected by Non Specific Low Back Pain

Protocol summary

Summary

The aim of present study is to compare the effects of standard rehabilitation protocol with and without exercise therapy in acute nonspecific low back pain. 43 volunteers suffering from acute nonspecific low back pain that do not have any acquired, congenital or traumatic spinal disorder and do not meet contraindications for spinal manipulation will be randomly assigned into experimental group (standard rehabilitation including spinal manipulation plus active exercise, n=21) and control group (standard rehabilitation including spinal manipulation, n=22) using random numbers table. After signing a detailed formal consent, demographic information will be obtained. Both groups will attend physical therapy clinic for eight sessions. Standard rehabilitation protocol will be the same in both groups and consists of TENS, education (pamphlet) and spinal manipulation. Spinal manipulation will be used for both groups in the first 2 sessions by an expert physical therapist certified in spinal manipulation techniques who is blind to the study groups. The manipulation technique will be subject-specific and will be decided according to the comprehensive clinical evaluation results. Immediate analgesic effect of spinal manipulation will be reported using visual analogue scale (VAS) for pain intensity before and immediately after the manipulations in either group. The experimental group will receive subject-specific exercise protocol for eight session while the control group will only receive the standard rehabilitation interventions. Pain intensity and disability score according to Oswestry Disability Index will be reported at the beginning, after the last therapeutic session, and after one month follow-up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080620888N6**
Registration date: **2016-10-18, 1395/07/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-10-18, 1395/07/27

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, Vice Chancellory of Research and Technology

Expected recruitment start date

2015-04-30, 1394/02/10

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effects of Standard Rehabilitation Protocol and Standard Rehabilitation Protocol in Combination with Exercise Therapy, on Functional Disability and Pain in Subjects Affected by Non Specific Low Back Pain

Public title

Comparing the Effects of Standard Rehabilitation Protocol and Standard Rehabilitation Protocol in Combination with Exercise Therapy in Subjects with Acute Low Back Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: meeting at least 5 items of following items: remaining pain even after 7 days of treatment; pain duration less than 6 weeks; no symptoms distal to the knee; one or more hypo-mobile segments in the lumbar spines; Oswestry disability score ≤ 25%; pain intensity ≥ 30% (Visual Analogue Scale). Exclusion criteria: spine fracture/surgery in the previous 6 months; pregnancy; neoplasia; infection of the spine; visceral pain; systemic disorders; radicular pain due to radiculopathy in last 6 months; sensory impairments; abnormal deep tendon reflexes or muscular weakness due to nerve compression; neurological claudication; psychiatric disorders; osteoporosis; corticosteroid therapy; receiving spinal manipulation previously for the same LBP episode; back pain; segmental spinal instability; administering narcotics; those who may not cooperate; those with contraindications for spinal manipulation; those who meet red flag conditions like fever; trauma; unusual weight loss.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization using random numbers table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Department of Physical Therapy, Muscoloskeletal Research Center, Faculty of Rehabilitation Sciences, Isfahan University of Medical Sciences, Hezar Jarib Ave.

City

Isfahan

Postal code

81745-164

Approval date

2014-04-26, 1393/02/06

Ethics committee reference number

394009

Health conditions studied

1

Description of health condition studied

Acute Nonspecific Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low Back Pain

Primary outcomes

1

Description

Pain

Timepoint

at the beginning, after first manipulation, after second manipulation, after the 8th therapeutic session, and at one month follow-up

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Functional Disability

Timepoint

at the beginning, after the 8th therapeutic session, and at one month follow-up

Method of measurement

Oswestry Disability Index (ODI)

Secondary outcomes

1

Description
Abdominal Muscle Endurance
Timepoint
at the beginning, after the 8th therapeutic session, and at one month follow-up
Method of measurement
Shirado Test

2

Description
Back Muscle endurance
Timepoint
at the beginning, after the 8th therapeutic session, and at one month follow-up
Method of measurement
Sorensen Test

Intervention groups

1

Description
Intervention Group: this group will receive standard treatment including education to stay active, self-management, lumbar school (a pamphlet is used), manipulation in the first two sessions and 30 minutes of transcotaneus electrical nerve stimulation (TENS) in each session. The standard protocol will be administered by the same physical therapist for all the subjects who is blind to the study design. The experimental group will also take part in 8 sessions of active exercises. The exercises are either flexor or extensor muscle endurance training according to the physical evaluation, subject' condition and subject' symptoms. Each exercise will be repeated three boats a day. The exercise will be cancelled and omitted if it aggravates the symptoms. Training progression is according to subjects' capabilities. A physical therapist who is blind to the study design will supervise the exercises. The exercises are kinesthetic (anterior and posterior pelvic tilt), mobility and flexibility (knee to chest, prone extension), muscle performance (drawing in maneuver, alternating flexion/extension of the upper extremities and heel slide) and functional (walking).
Category
Rehabilitation

2

Description
Control Group: this group will receive standard treatment including education to stay active, self-management, lumbar school (a pamphlet is used), manipulation in the first two sessions and 30 minutes of transcotaneus electrical nerve stimulation (TENS) in each session. The standard protocol will be administered by the same physical therapist for all the subjects who is blind to the study design.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Physical Therapy Clinic of Petroleum Industry Health Organizaion
Full name of responsible person
Sajjad Amel Eini
Street address
Number 9, Sadeghi Street, Water Boulvard
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Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences, Vice Chancellory of Research and Technology
Full name of responsible person
Dr. Mehdi Nemat Bakhsh
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Vice Chancellory of Research and Technology, Isfahan University of Medical Sciences, Hezar Jarib Ave.
City
Isfahan
Grant name
Grant code / Reference number
394009
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences, Vice Chancellory of Research and Technology
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
Muscoloskeletal Research Center, Department of Physical Therapy, Faculty of Rehabilitation Sciences,
Full name of responsible person

Dr. Zahra Sadat Rezaeian

Position

PhD, Assistant Professor

Other areas of specialty/work

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http://scholar.google.com/citations?user=FXzUASAAAAAJ&hl=en

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