

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Zahra Sadat Rezaeian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5042

Email address

zrezaeian@rehab.mui.ac.ir

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 $\leq 25\%$; pain intensity $\geq 30\%$ (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, Musculoskeletal 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 transcutaneous 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 times 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 transcutaneous 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 Organization

Full name of responsible person

Sajjad Amel Eini

Street address

Number 9, Sadeghi Street, Water Boulevard

City

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

Street address

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

Musculoskeletal 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

Street address

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

City

Isfahan

Postal code

81745-164

Phone

00983137925012; 00983137925042

Fax

+98 31 3668 7270

Email

zrezaeian@yahoo.com; zrezaeian@rehab.mui.ac.ir

Web page address

<http://scholar.google.com/citations?user=FXzUASAAA-AAJ&hl=en>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Musculoskeletal 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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Email

zrezaeian@yahoo.com; zrezaeian@rehab.mui.ac.ir

Web page address

<http://scholar.google.com/citations?user=FXzUASAAA-AAJ&hl=en>

Person responsible for updating data

Contact

Name of organization / entity

Musculoskeletal 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

Street address

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

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Email

zrezaeian@yahoo.com; zrezaeian@rehab.mui.ac.ir

Web page address

<http://scholar.google.com/citations?user=FXzUASAAA-AAJ&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