

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Evaluation of efficacy of Manipulation in patients with subacute and chronic radicular low back pain in 501 hospital in 1396.

Protocol summary

Study aim

Evaluation of efficacy of Manipulation in patients with subacute and chronic radicular low back pain in 501 hospital in 1396.

Design

Clinical trial with a control group with parallel groups and randomized.

Settings and conduct

This study will conducted as a clinical trial in Imam Reza Hospital and patients with low back pain. This will be in phase 3 and conducted in 44 patients divided by block method into two groups, 22 patients in intervention group and receive manipulation, and 22 patients in control and receiving routine treatment. Based on this, at first, after end of treatment and 3 months after starting treatment, low back pain is assessed by VAS method.

Participants/Inclusion and exclusion criteria

Patients with unilateral radicular low back pain in more than 4 weeks and refer to 501 Physical Medicine Hospital's with satisfaction to participate in the study are included in study, also patients with underlying illness and impossibility of manipulation are excluded from the study.

Intervention groups

In control group, therapeutic are performed with acetaminophen 325 mg and gabapentin 100 mg every 12 hours and physiotherapy of ten sessions of HP, TENSE, US, Core EXC and exercise, and in intervention group with manipulation with mine approach, including 3 sessions at intervals of one week were done.

Main outcome variables

Low Back Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190109042315N1**

Registration date: **2019-04-23, 1398/02/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-23, 1398/02/03**

Update count: **0**

Registration date

2019-04-23, 1398/02/03

Registrant information

Name

Seyede Zahra Hosseini Ghasabmahale

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4382 3476

Email address

sh.najafi@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-20, 1397/12/29

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of Manipulation in patients with subacute and chronic radicular low back pain in 501 hospital in 1396.

Public title

Evaluation of efficacy of Manipulation in patients with

subacute and chronic radicular low back pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Single-sided radicular low back pain Back pain over 4 weeks Referring to the Medical Physics Clinic of 501 hospital Satisfaction to participate in the study
Exclusion criteria:
Severe osteoporosis Unstable fracture Multiple myeloma Osteomyelitis Primary tumors of the bone Paget Any progressive neurological defect Spinal cord tumors Cauda Equina Syndrome Joint hypermobility Rheumatoid arthritis and non-mechanical low back pain Inflammatory phase of ankylosing spondylitis Psoriatic arthritis Reiter's disease Anticoagulant therapy Congenital hemorrhagia History of disc surgery Spondylosis and spondylolisthesis Congenital malformation Acute radiculopathy Taking an analgesic drug other than acetaminophen and gabapentin No pain free direction for maneuvering Bilateral radiculopathy Hernia intense (extrusion) Pregnancy

Age
From **25 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple randomization is done with sealed envelope tools in such a way that the letters A and B are inserted in the envelopes and patients are asked to select an envelope that the intervention group A and the group B will be as case group.

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 committee of Medical University for the Islamic Republic of Iran's Army

Street address

Tehran, West Fatemi St., Etemadzadeh Avenue, Medical University for the Islamic Republic of Iran's Army

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2018-06-02, 1397/03/12

Ethics committee reference number

IR.AJAUMS.REC.1397.008

Health conditions studied

1

Description of health condition studied

Radicular low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

low back pain

Timepoint

At first, immediately after the end of treatment and 3 months after the end of treatment

Method of measurement

Using the Visual Analogue Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Therapeutic treatments are performed with acetaminophen 325 mg and gabapentin 100 mg every 12 hours and physiotherapy of ten sessions of HP, TENSE, US, Core EXC and exercise with manipulation with mines approach, including 3 sessions at intervals of one week.

Category

Rehabilitation

2

Description

Control group: Therapeutic treatments are performed with acetaminophen 325 mg and gabapentin 100 mg every 12 hours and physiotherapy of ten sessions of HP, TENSE, US, Core EXC and exercise.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Dr. Sharif Najafi

Street address

Tehran, West Fatemi St., Shahid Etemadzadeh, Imam Reza - 501 Army Hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Mostafa Shahrezaee

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moshahrezayee@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Artesh University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Seyyede Zahra Hosseini

Position

Resident of Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Sharif Najafi

Position

Assistant Professor of Physical Medicine and Rehabilitation

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Latest degree

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Other areas of specialty/work

Physical Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available