Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Investigating the Effect of Traditional Iranian Manual Technique on Pain and Disability in Patients with Chronic Low Back Pain

Protocol summary

Study aim
This study was designed with the aim of determining the effect of traditional Iranian manual techniques on the pain and disability of patients with chronic back pain.

Design
The clinical trial has a control group, with parallel, double-blind, randomized groups. The patients will be randomly divided into two groups according to the order of referral. In the intervention group, the manual technique is performed once for each person, and for the sham group, ineffective manipulation is performed at an unrelated point on the body.

Settings and conduct
Patients will be divided into two parts, treatment and placebo (blinding of the patient and the researcher), and will be subjected to the main manipulation maneuver or placebo manipulation using the table of random numbers.

Participants/Inclusion and exclusion criteria
All adults between 20 and 70 years old with chronic low back pain, provided that they have not received serious treatment or have dangerous pathology. (The list of serious treatments and dangerous pathologies are in the inclusion and exclusion criteria)

Intervention groups
Two groups: 1: intervention group (Iranian manual technique) and 2: control group (placebo (fake) manual technique)

Main outcome variables
VAS (Visual Analogue Scale) and Rowland-Morris questionnaire; the number of diclofenac tablets used

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230502058050N1**
Registration date: **2023-05-22, 1402/03/01**
Registration timing: **prospective**

Last update: **2023-05-22, 1402/03/01**
Update count: **0**

Registration date
2023-05-22, 1402/03/01

Registrant information
Name
Alireza Abbassian
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-05, 1402/03/15

Expected recruitment end date
2024-08-05, 1403/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the Effect of Traditional Iranian Manual Technique on Pain and Disability in Patients with Chronic Low Back Pain

Public title
Investigating the Effect of Traditional Iranian Manual Technique on Pain and Disability in Patients with Chronic

Low Back Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Personal and informed consent of the individual to participate in the research project Presence of chronic low back pain (history of more than three months of pain) Age range between 20 and 70 years old

Exclusion criteria:

The presence of paresthesia and radicular pain and any specific pathology such as nerve root inflammation, spinal canal stenosis, spondylolysis, spondylolisthesis, vertebral fracture (clinical examination by a neurosurgeon to rule out any pathology) Non-mechanical back pain (wakes the patient up at night or causes pain and dryness in the morning) Fever, sweating and unexplained weight loss in the last few months Long-term corticosteroid therapy The symptoms of horse tail syndrome include numbness and weakness of both legs, pain in the anus, numbness of the perineum, paralysis of the sphincters.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Using simple randomization with a table of random numbers to divide clients into two groups in the order of admission

Blinding (investigator's opinion)

Double blinded

Blinding description

By using a table of random numbers and inserting a random code on the paper inside the numbered envelopes, the patients are divided into two intervention and placebo groups (54 envelopes with even codes and 54 envelopes with odd codes are prepared). At the beginning of the intervention, the therapist chooses in which group (an even number or an odd number) to perform Iranian medicine manipulation and in which group to perform placebo manipulation (for example, if the code inside the envelope was an even number, the main manipulation will be performed on them, and in the case of an odd number, manipulation placebo will be done). The patient's name and surname are entered in a separate table along with the assigned code. In this way, the doctor treating the patient was not blinded, but the patient, the researcher, the author of the article, and the analyst of the results were blinded to the data.

Placebo

Used

Assignment

Parallel

Other design features

The calculated sample size in each group is 54 people, which is 60 people in each group by calculating a ten percent loss.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Research School of Pharmaceutical Sciences, Tehran University of Medical Science

Street address

Poursina Avenue, Tehran University of Medical Sciences, Faculty of Pharmacy, The Institute of Pharmaceutical Sciences (TIPS)

City

Tehran

Province

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Postal code

1417613151

Approval date

2023-04-29, 1402/02/09

Ethics committee reference number

IR.TUMS.TIPS.REC.1402.019

Health conditions studied

1

Description of health condition studied

Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Intensity of pain

Timepoint

Before and immediately after the intervention and one week after the intervention

Method of measurement

VAS questionnaire

2

Description
Degree of disability
Timepoint
Before and one week after the intervention
Method of measurement
Roland Morris questionnaire

Secondary outcomes

1

Description
The number of diclofenac tablets taken
Timepoint
One week after the intervention
Method of measurement
Counting and averaging the number of pills taken daily

Intervention groups

1

Description
Intervention group: Iranian manual technique group, First, the patient lies on the examination bed in a supine position and both legs are placed together, and examinations such as: comparison of the length of the legs are performed (the distance between the two landmarks from the anterior superior iliac crest to the inner ankle in two side) and if this size is different, the person can be included in the study by considering other entry criteria. To perform the technique, the patient is placed on his side on the examination bed and the therapist holds the patient's chest and shoulder steady with one hand and puts pressure on the patient's back and pelvis with the other hand. The same technique is also performed lying on the opposite side.
Category
Treatment - Other

2

Description
Placebo group: Sham manipulation technique, In this group, the patient first lies on the examination bed in a supine position and both legs are placed together, and examinations such as: comparison of the length of the legs are performed (the distance between the two landmarks from the anterior superior iliac crest to the ankle internal on both sides) and if this size is different, the person can be included in the study considering other inclusion criteria. To perform the technique, the patient is placed on his side on the examination bed and slight pressure is applied on the iliac crest and tibia bone (bilaterally).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahmadiyya Clinic, Faculty of Persian Medicine, Tehran University of Medical Sciences
Full name of responsible person
Alireza Abbassian
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Alireza Abbassian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about its main outcomes can be shared.

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

All people

Under which criteria data/document could be used

The data can be used for scientific analysis.

From where data/document is obtainable

Our email: abbasian@sina.tums.ac.ir

What processes are involved for a request to access data/document

After viewing the resume and the reason for the request, it will be reviewed and sent within 3 months.

Comments