

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the effect of manipulation derived from traditional medicine on low back pain spread to the lower limbs

Protocol summary

Study aim

Assessing the impact of a traditional medicine-derived manipulation technique (Ghamz therapy) on pain intensity and disability in patients suffering from chronic back pain extending to the lower limbs.

Design

This study is a single-arm, open-label, non-randomized clinical trial focusing on patients with chronic low back pain that radiates to the lower limbs. It includes 15 participants.

Settings and conduct

Patients suffering from chronic back pain with lower extremity referral who visit the Faculty of Traditional Medicine at Shahid Beheshti University of Medical Sciences during the 2024-2025 period will be included in the study, provided they meet the established inclusion criteria

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with chronic back pain lasting more than 8 weeks, radiating to the lower limbs, who have a pain intensity of 3 or greater on the visual analog scale (VAS). Exclusion Criteria for Participation in the Study: Having surgical indications

Intervention groups

A group includes patients with chronic low back pain that spreads to the lower limbs, who are included in the study based on the inclusion criteria. The intervention involves the use of a manual technique rooted in traditional medicine known as "Ghamz therapy". This method includes applying pressure to specific points in the lower back and lower limbs using a specialized wooden tool, which facilitates the release of myofascial spasms. The intervention consists of three sessions scheduled on day 0, day 7, and day 37 for all patients.

Main outcome variables

Pain intensity assessed using the Visual Analog Scale (VAS); Patient disability level measured using the Roland-Morris Disability Questionnaire score; Back flexibility determined through the Fingertips-to-Floor test; Patients'

quality of life evaluated using the World Health Organization Quality of Life Questionnaire (Short Form-WHOQOL).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190112042333N2**

Registration date: **2024-10-01, 1403/07/10**

Registration timing: **registered_while_recruiting**

Last update: **2024-10-01, 1403/07/10**

Update count: **0**

Registration date

2024-10-01, 1403/07/10

Registrant information

Name

Sajjad Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

drsadeghi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-30, 1403/07/09

Expected recruitment end date

2024-12-20, 1403/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of manipulation derived from traditional medicine on low back pain spread to the lower limbs

Public title
Effect of manipulation derived from traditional medicine on low back pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Low back pain radiating to the one-sided lower limb
Completion of the informed consent process to participate in the study
Onset of pain at least 8 weeks ago (constant or intermittent)
BMI between 18-35
Pain intensity VAS score ≥ 3
Exclusion criteria:
Malignancy
Pregnancy
Symptoms of Cauda equina syndrome include numbness and weakness of both legs, pain spread to the anus, numbness of the perineum, paralysis of the sphincters.
History of rheumatic diseases
Presence of paresthesia and specific pathology including spondylolysis, spondylolisthesis, vertebral fracture
Suffering from all types of myopathies

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University of Medical Sciences

Street address
Shahid Beheshti University of Medical Sciences, Arabi St., Student Blvd., Valenjak.

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2024-08-18, 1403/05/28

Ethics committee reference number
IR.SBMU.RETECH.REC.1403.265

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

Pain intensity

Timepoint

Before the start of the intervention, one week after the intervention and 37 days after the start of the intervention

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Quality of life

Timepoint

Before the start of the study and 37 days after the start of the study

Method of measurement

WHO quality of life questionnaire (Short Form-WHOQOL)

3

Description

Diability

Timepoint

Before the start of the study and 37 days after the start of the study

Method of measurement

Roland-Morris disability questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Administering a technique from Traditional Medicine known as "Ghamz therapy", which involves applying pressure with a specially designed wooden tool to targeted areas of the patient's back and lower limbs. This treatment consists of three sessions: one at the beginning of the visit, another one week later, and a final session 37 days after the intervention begins

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Traditional Medicine, Shahd Beheshti
University of Medical Sceinces

Full name of responsible person

Sajjad Sadeghi

Street address

School of Traditional Medicine Shahid Beheshti
University of Medical Sciences No.8 Shams Alley, Vali-
e-Asr Street Tehran, Iran

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Postal code

1516745811

Phone

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Email

itm.beheshti@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin zarghi

Street address

5th Floor, Bldg No.2 Shahid Beheshti University of
Medical Sciences, Arabi Ave, Daneshjoo Blvd,
Velenjak

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1983963113

Phone

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Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sajjad Sadeghi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

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Person responsible for scientific inquiries

Contact

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main outcomes of the study

When the data will become available and for how long

6 months after the publication of the research paper

To whom data/document is available

Faculty members of universities

Under which criteria data/document could be used

With the aim of modeling to conduct a similar study Save
translation

From where data/document is obtainable

Email of the chief researcher to the following address:
Drsadeghi@sbmu.ac.ir

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

Submission of the request via email, obtaining approval
from the center's research council, and then receiving
the requested information.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sajjad Sadeghi

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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