Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 questioner (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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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

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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

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Person responsible for updating data

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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