

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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@sbm.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  $\geq 3$   
**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 Sciences

#### 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1516745811

#### Phone

+98 21 8877 6028

#### 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1983963113

#### Phone

+98 21 2243 9780

#### Email

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

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

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#### Phone

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#### Email

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Sajjad Sadeghi

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

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**Full name of responsible person**

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**Position**

Assistant Professor

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**Email**

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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@sbm.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**