Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of an Iranian Traditional Medicine Based Manipulation (Hasanzadeh Technique) on Clinical Symptoms and Quality of Life of Patients Chronic Radicular Low Back Pain compared to Physiotherapy.

Protocol summary

Study aim

Evaluation of an Iranian Traditional Medicine Based Manipulation (Hasanzadeh Technique) on Clinical Symptoms and Quality of Life of Patients Chronic Radicular Low Back Pain compared to Physiotherapy

Design

70 patients with chronic radicular back pain who meet the inclusion criteria according to examination and paraclinical data will be enrolled in the study and randomly divided into two groups; one group will receive 10 consecutive one-hour physiotherapy sessions three times a week, and the second group will receive 3 sessions of Ghamz according to the Hassanzadeh method on the first day, day 8, and day 38.

Settings and conduct

Data collection will be conducted at Shahid Beheshti College of Traditional Iranian Medicine and Baqiyatullah Al-Azam Hospital. There is no possibility of blinding the study, so the data analyst will be blinded and efforts will be made to avoid providing biased explanations and any attempt to change the attitude of the study patients.

Participants/Inclusion and exclusion criteria

Back pain radiating to the lower extremities unilaterally Completed an informed consent form for study entry Pain onset at least 8 weeks ago (continuous or intermittent) Age between 18-60 years BMI between 18-35 Pain intensity VAS score ≥ 3

Intervention groups

70 patients with chronic radicular back pain who meet the inclusion criteria according to examination and paraclinical data will be enrolled in the study and randomly divided into two groups; one group will receive 10 consecutive one-hour physiotherapy sessions three times a week, and the second group will receive 3 sessions of Ghamz according to the Hassanzadeh method on the first day, day 8, and day 38.

Main outcome variables

Visual analogue scale (VAS) pain score in the lower extremities; disability; quality of life; age; education; gender; weight; Fingertips to Floor (F2F) test; analgesic use; satisfaction with treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250205064650N1**
Registration date: **2025-03-13, 1403/12/23**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-13, 1403/12/23**
Update count: **0**

Registration date

2025-03-13, 1403/12/23

Registrant information

Name

Bahman Rokhafrooz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

rokhafruz.bahman@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-19, 1403/12/01

Expected recruitment end date

2025-09-21, 1404/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of an Iranian Traditional Medicine Based Manipulation (Hasanzadeh Technique) on Clinical Symptoms and Quality of Life of Patients Chronic Radicular Low Back Pain compared to Physiotherapy.

Public title

The effect of manipulation derived from traditional medicine on low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

unilaterally radicular low back pain Completed informed consent to enter the study Pain onset at least 8 weeks ago (continuous or intermittent) Age between 18-60 years Pain severity VAS score ≥ 3

Exclusion criteria:

Previous surgical history or RCLBP Presence of paresthesia and specific pathology including spondylolysis, spondylolisthesis, vertebral fracture Having muscle wasting and weakness of the lower limbs• Having various myopathies Fever, sweating and unexplained weight loss in the last few months Long-term corticosteroid therapy Symptoms of cauda equina syndrome including numbness and weakness of both legs, pain radiating to the anus, perineal numbness, sphincter paralysis Having malignancy Having an indication for emergency surgery with criteria including acute onset of motor deficit, perineal numbness, and bladder and bowel dysfunction in cauda equina syndrome Severe osteoporosis according to history if there is a bone density scan T-score less than -2.5 Vascular problems of the lower extremities Diabetes: Given that in this study, neuromuscular examination is not performed and there is no estimate of nerve involvement, diabetic patients were excluded from this study History of hip fracture and dislocation Known psychological disorders based on the patient's history including major depression, severe anxiety, psychosis, schizophrenia, bipolar disorder, and personality disorder History of surgery and muscle and fascial tears in the lower extremities Patients treated with blood thinners including warfarin and heparin History of use of injectable opioids History of rheumatic diseases

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: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to assign patients to two treatment groups, the Blocked Randomization method with blocks of four will be used. First, six possible states of blocks (BAAB, ABBA, BABA, BBAA, ABAB, AABB) are listed and a number from one to six is assigned to each block. Then, numbers between one and six are randomly selected using a table of random numbers, and then people are assigned to the Manipulation (A) and Physiotherapy (B) group based on the block corresponding to the selected number, and this work is done until completion. The sample size will continue.

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 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

2025-01-12, 1403/10/23

Ethics committee reference number

IR.SBMU.RETECH.REC.1403.695

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
Pain intensity
Timepoint
Before the start of the intervention and 38 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 38 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 38 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

2

Description
Control group: Patients in the physiotherapy group will receive 10 consecutive one-hour physiotherapy sessions three times a week. Each session will include hot pack therapy (heat at 71-74°C for 20 minutes), transcutaneous electrical nerve stimulation (TENS; at a frequency of 100 Hz for a total of 20 minutes, intensity adjusted according to patient tolerance), and ultrasound (1 MHz, 1.5 W/cm2 for a total of 10 minutes) applied to the lumbar region.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti School of Traditional Iranian Medicine
Full name of responsible person
Bahman Rokhafrooz
Street address
Department of Traditional Medicine, Shahid Beheshti University of Medical Sciences, Shams Alley, Vali Asr ave, Tehran, Iran
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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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
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5th Floor, Bldg No.2 Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak
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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
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
Bahman Rokhafrooz
Position
student
Latest degree
Medical doctor
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: Rokhafruz.bahman@gmail.com

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