Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the efficacy of Ghamz therapy for the improvement of clinical symptoms and quality of life in patients with mild to moderate knee osteoarthritis

Protocol summary

Study aim
Evaluation of the efficacy of Ghamz therapy for the improvement of clinical symptoms and quality of life in patients with mild to moderate knee osteoarthritis

Design
A phase 3, single-blind, randomized, controlled clinical trial of 72 patients Randomization will be by block method

Settings and conduct
In the medical center, A statistician uses a computer to generate the random allocation sequence, and sequentially numbered, opaque, sealed envelopes are used to conceal the allocation sequence.

Participants/Inclusion and exclusion criteria
Inclusion Criteria From 36 years old and above؛ Knee pain for more than 3 months with a score of at least 3 on the VAS scale ؛ Diagnosis of knee osteoarthritis based on ACR clinical and radiographic criteria؛ Grade I or II on knee radiography according to the Kellgren–Lawrence grading system ؛Ability to perform the desired exercises؛ Exclusion Criteria Use of sedatives, narcotics, muscle relaxants, or other undefined analgesics ؛within 2 weeks prior to the study start؛ Intra-articular steroid injection within 3 weeks prior or systemic steroid ؛injection within 2 weeks prior to the study start ؛ PRP injection within the past 6 months؛ Ozone therapy within the past 3 months؛ Hyaluronic Acid gel injection within the past 6 months ؛Topical herbal treatment, thermal therapy, or acupuncture within 2 weeks prior to the study start؛ Presence of severe neuropathy or severe neuromuscular disease ؛ Presence of any other source of knee pain besides osteoarthritis؛ Open wound on the knee surface؛ History of severe knee trauma or knee/lower limb surgery؛ Malignancies؛

Intervention groups
In both groups, exercise was combined with Ghamz therapy in the inter vention group.

Main outcome variables
WOMAC questionnaire score, pain, knee range of motion (ROM), quality of life, and diclofenac consumption

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20251001067443N1**
Registration date: **2025-11-27, 1404/09/06**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-27, 1404/09/06**
Update count: **0**

Registration date
2025-11-27, 1404/09/06

Registrant information
Name
alireza azadkhani
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-11-22, 1404/09/01
Expected recruitment end date
2026-06-21, 1405/03/31
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the efficacy of Ghamz therapy for the improvement of clinical symptoms and quality of life in patients with mild to moderate knee osteoarthritis

Public title
Can massage therapy help improve the pain and discomfort caused by knee osteoarthritis and increase quality of life?
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
From 36 years old and above Knee pain for more than 3 months, at least 3 on the VAS scale in activities such as going up and down stairs or sitting and squatting Diagnosis of knee osteoarthritis based on clinical criteria + ACR radiography Grade one or two on knee radiographs based on the Kellgren Lawrence system Ability to perform the desired exercises
Exclusion criteria:
Use of sedatives, narcotics, muscle relaxants, or other undefined analgesics within 2 weeks prior to the start of the study. Intra-articular steroid injection within 3 weeks or systemic steroid administration within 2 weeks prior to the start of the study. Platelet-rich plasma (PRP) injection within the past 6 months. Ozone therapy within the past 3 months. Intra-articular injection of hyaluronic acid gel within the past 6 months. Use of topical herbal treatments, thermal therapy, or acupuncture within 2 weeks prior to the start of the study. Presence of severe neuropathy or significant neuromuscular disease that prevents the patient from tolerating the intervention. Presence of knee pain due to causes other than osteoarthritis. Presence of an open wound on the knee surface. History of severe knee trauma or previous knee or lower limb surgery. History of malignancy.
Age
From **36 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed using a block randomization method with blocks of four and an allocation ratio of 1:1. A statistician will use a computer to generate the random allocation sequence, and no other study personnel will have access to this sequence. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes (SNOSE) to maintain blinding of the allocation sequence.
Blinding (investigator's opinion)
Single blinded
Blinding description
Outcome evaluators have no knowledge of the type of treatment or treatment group administered and only receive the data.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee Faculty of Medicine Shahed University
Street address
Persian Gulf Highway (beginning of Tehran-Qom Freeway), opposite the Holy Shrine of Imam Khomeini (RA), Shahed University, Faculty of Medicine
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Province
Tehran
Postal code
3319118651
Approval date
2025-10-13, 1404/07/21
Ethics committee reference number
IR.SHAHED.MED.REC.1404.076

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis
ICD-10 code
M17.0
ICD-10 code description
Bilateral primary osteoarthritis of knee

Primary outcomes

1

Description
WOMAC questionnaire score
Timepoint
Before the start of the intervention, after 7 weeks of intervention, and at the end of week 11
Method of measurement

WOMAC questionnaire

2

Description
Pain
Timepoint
Before the start of the intervention, after 7 weeks of intervention, and at the end of week 11
Method of measurement
Visual Analysis Score(VAS)

3

Description
Knee range of motion (ROM)
Timepoint
Before the start of the intervention, after 7 weeks of intervention, and at the end of week 11
Method of measurement
Goniometer

Secondary outcomes

1

Description
Quality of Life
Timepoint
Before the start of the intervention, after 7 weeks of intervention, and at the end of week 11
Method of measurement
Quality of Life Questionnaire(SF12)

2

Description
Diclofenac consumption
Timepoint
Before the start of the intervention, after 7 weeks of intervention, and at the end of week 11
Method of measurement
Patient self-report

Intervention groups

1

Description
Intervention group: Ghamz (a type of deep tissue massage applied to specific points of the body) will be administered for 7 weeks, with one session per week. In parallel, home-based active exercises will be taught and performed for 7 weeks, three times daily (morning, noon, and night).
Category
Treatment - Other

2

Description
Control Group:In this group, patients will not receive Ghamz therapy during the study period. After 7 weeks, the control group will also undergo Ghamz therapy—similar to the intervention group—for 7 sessions, once per week. However, in the control group as well, home active exercises will be taught and performed three times daily (morning, noon, and night) from the beginning of the study, and will continue until the end of the treatment period (7 weeks without Ghamz therapy during the study, and 7 weeks with Ghamz therapy after the study).
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Abolfazl (AS) Specialized Medical Center
Full name of responsible person
Alireza Azadkhani
Street address
West Marzdaran Street, not reaching Ashrafi Esfahani, Abolfazl Street, Shahid Redaei Alley, second floor of the mosque
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2

Recruitment center
Name of recruitment center
Ahmadiyeh Health Center, School of Traditional Iranian Medicine, Iran University of Medical Sciences
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No. 27, North Sarparast Street, at the beginning of West Taleghani Street, Palestine Square
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Web page address

3

Recruitment center

Name of recruitment center
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Full name of responsible person
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No. 79, Corner of Sahel Alley, Razi Street, Valiasr Intersection, Enghelab Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahed University

Full name of responsible person
Hamed Sajedi

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Shahed University, opposite the Holy Shrine of Imam Khomeini (RA), Khalij-e Fars Highway (Beginning of Tehran-Qom Freeway)

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Email
publicrelation@shahed.ac.ir

Web page address
https://shahed.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Shahed University

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
Shahed University

Full name of responsible person
Alireza Azadkhani

Position
Ph.D. candidate

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Position
Ph.D. candidate

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Person responsible for updating data

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Position
Ph.D. candidate

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
The study results will be published as an article in scientific research journals.

When the data will become available and for how long
After the results are published.

To whom data/document is available
Journal reviewers

Under which criteria data/document could be used
No analysis is allowed.

From where data/document is obtainable
Refer to the principal investigator

What processes are involved for a request to access data/document
The request is sent to the principal investigator via email, stating the reason. It is sent after 2 weeks if the data is approved.

Comments