

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of 12 point inferior extremity gham on knee pain relief

Protocol summary

Study aim

Evaluation of the effect of 12-point foot (lower extremity) gham in the treatment of knee pain (knee pain)

Design

This study is double-blind, placebo-controlled, randomized clinical trial

Settings and conduct

This study is conducted in several clinical centers.

Participants/Inclusion and exclusion criteria

Included criteria: complete vigilance and satisfaction; age over 35 years old; diagnosis of osteoarthritis according to the American Society of Rheumatology (Having knee pain and having at least 5 of the 8 cases listed below: Age greater than 50 years; Stiffness < 30 minutes; Crepitus; Bony tenderness; Bony enlargement; No palpable warmth; ESR < 40 mm/hr; Rheumatoid Factor (RF) < 1:40); not using a variety of complementary therapies during the previous three months; lack of personalized sedative medications and drug by the patient; absence of severe neuropathy in the patient; healthy areas under massage; lack of mental retardation, blindness and deafness. The absence of rheumatoid arthritis, fibromyalgia, acute or recurrent pseudovirus, malignancy, internal disease, Such as kidney or liver disorder, gastrointestinal bleeding, asthma requiring corticosteroid administration; no use of corticosteroid in less than 5 weeks, injection of knee depocorticosteroid in less than 3 months old or intra-articular hyaluronate in less than 6 months; lack of arthroscopy over the past year; no significant damage to the knee in less than 6 months; insensitivity and ulcer in the knee; ability to learn 12 gham points.

Intervention groups

12-point foot (lower extremity) gham

Main outcome variables

1- Knee injury and Osteoarthritis Outcome Score 2- VAS Questionnaire 3- Taking the Diclofenac drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181130041802N1**

Registration date: **2019-02-03, 1397/11/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-03, 1397/11/14**

Update count: **0**

Registration date

2019-02-03, 1397/11/14

Registrant information

Name

Maryam Alinaghizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2296 4390

Email address

forqanimhd@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-22, 1397/06/31

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of 12 point inferior extremity gham on knee pain

relief

Public title

Ghams inferior extremity on knee pain relief

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Complete vigilance and satisfaction. Age over 35 years old. Diagnosis of osteoarthritis according to the American Society of Rheumatology: Having knee pain and having at least 5 of the 8 cases Not using a variety of complementary therapies during the previous three months Lack of personalized sedative medications and drug by the patient The absence of severe neuropathy in the patient. Healthy areas under massage Lack of mental retardation, blindness and deafness. The absence of rheumatoid arthritis, fibromyalgia, acute or recurrent pseudoravirus, malignancy, internal disease, Such as kidney or liver disorder, gastrointestinal bleeding, asthma requiring corticosteroid administration Non-use of corticosteroid in less than 5 weeks, injection of knee depocorticosteroid in less than 3 months old or intra-articular hyaluronate in less than 6 months A lack of arthroscopy over the past year No significant damage to the knee in less than 6 months Insensitivity and ulcer in the knee. Ability to learn 12 ghams points

Exclusion criteria:

Using a variety of complementary therapies during the previous three months Personalized sedative medications and drug by the patient Severe neuropathy in the patient Having mental retardation, blindness and deafness. having the rheumatoid arthritis, fibromyalgia, acute or recurrent pseudoravirus, malignancy, internal disease, Such as kidney or liver disorder, gastrointestinal bleeding, asthma requiring corticosteroid administration Use of corticosteroid in less than 5 weeks, injection of knee depocorticosteroid in less than 3 months old or intra-articular hyaluronate in less than 6 months Arthroscopy over the past year Significant damage to the knee in less than 6 months Sensitivity and ulcer in the knee

Age

From **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization, 80 numbers were written on 80 paper and placed inside a bag. The numbers were randomly and blindly removed from the bag. 40 first

issues as intervention group and 40 second ones as control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both participants, as well as researchers or evaluators, are unaware of the allocation of study groups.

Placebo

Used

Assignment

Parallel

Other design features

Designed for the first time

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Sixth Floor, Central Office of Tehran University of Medical Sciences, Ghodss St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-08-31, 1397/06/09

Ethics committee reference number

IR.TUMS.VCR.REC.1397.388

Health conditions studied

1

Description of health condition studied

Knee Pain

ICD-10 code

M17.9

ICD-10 code description

Osteoarthritis of knee, unspecified

Primary outcomes

1

Description

Knee Pain

Timepoint

Before the study 0, Sixth day, Fourteenth day

Method of measurement

Knee injury and Osteoarthritis Outcome Score, Visual Analogue Scale

Secondary outcomes

1

Description

Diclofenac drug intake

Timepoint

Fourteenth day

Method of measurement

Number

Intervention groups

1

Description

Intervention group:

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahmadiieh traditional medicine treatment center

Full name of responsible person

Maliheh Tabraee

Street address

Sarparast st., Palestine Square

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Tehran

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadali Sahraian

Street address

Keshavarz Blvd., Ghods St., Central Organization of the University, 6th floor of Research and Technology Department

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rmo@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Maryam Alinaghizadeh

Position

Ph.D. Candidate of Traditional Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All Data

When the data will become available and for how long

6 months after printing results

To whom data/document is available

All People

Under which criteria data/document could be used

Maintaining intellectual rights

From where data/document is obtainable

Maryam Alinaghizadeh

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

A written request by sending an email and receiving an answer within 10 days

Comments