Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Assessment of the effect of Leech Therapy on knee osteoarthritis pain and daily functioning of the elderly

Protocol summary

Study aim
Assessment of the effect of Leech therapy on knee osteoarthritis pain and daily functioning of the elderly

Design
Clinical trial with control group, single group, no blinding, randomized stratified block, phase 2 on 80 patients, A random number table is used for randomization

Settings and conduct
After referring the elderly to the orthopedic clinic and confirming the diagnosis of osteoarthritis by an orthopedic specialist, explaining the research objectives for the elderly, obtaining informed consent, dividing into two groups of 40 people with random stratified obstruction and evaluating pain, joint stiffness and physical function with Osteoarthritis Index of Western Ontario and McMaster Universities

Participants/Inclusion and exclusion criteria
Inclusion criteria: Being 60-74 years old Having grade 3 osteoarthritis Having moderate pain based on visual analog criteria with a score of (4-7) Having a BMI (body mass index) above 18.5 and below 30 Have a daily performance score above 34 Exclusion criteria: Creating acute medical conditions Elderly deaths during study time

Intervention groups
In the intervention group, a 30-minute leech treatment session using 6 to 8 leeches will be performed in a clean and secluded room while maintaining the patient's privacy in the traditional medicine clinic environment. Before using leeches, the skin in the tibio-femoral area is rinsed with a sharp, sterile needle after rinsing with serum to release a few small drops of blood to stimulate the leeches to suck blood and then 6 to 8 leeches will be placed in the area for 30 minutes. The control group receives routine treatment as usual and does not receive any intervention from the researcher.

Main outcome variables
change in pain; change in joint dryness; reducing the poly pharmacy phenomenon; improve the daily functioning of the elderly and improve the quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170514033961N8**
Registration date: **2021-11-08, 1400/08/17**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-08, 1400/08/17**
Update count: **0**

Registration date
2021-11-08, 1400/08/17

Registrant information

Name
Mandana Saki

Name of organization / entity
Lorestan University of Medical Sciences

Country
Iran (Islamic Republic of)

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m.saki@modares.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-07, 1400/07/15

Expected recruitment end date
2021-12-06, 1400/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment of the effect of Leech Therapy on knee osteoarthritis pain and daily functioning of the elderly

Public title
"Evaluation of the effect of Leech Therapy on knee osteoarthritis"

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age 60-74 (young elderly) Independence of others in daily activities Lack of neurological diseases associated with movement and balance disorders Having grade 3 (middle class) osteoarthritis according to the American College of Rheumatology classification criteria Having moderate pain based on visual analog scale with a score of (4-7) Failure to perform physiotherapy and knee surgery in the last 12 months Having satisfaction consciously to participate in the study No coagulation disorders and cardiovascular disease according to clinical history No use drugs No history of joint replacement in the lower limb No intra-articular injection of steroids in the last 6 months Having a BMI (body mass index) above 18.5 and below 30 Have a daily performance score above 34 Do not use complementary medicine methods and herbs in the field of osteoarthritis

Exclusion criteria:
Occurrence of acute medical conditions such as anaphylactic shock and stroke during the study Elderly deaths during the study Withdrawal from the study despite initial agreement Sensitivity to leeches Existence of cognitive disorders based on the physician's opinion and the patient's previous medical history Secondary osteoarthritis in rheumatic diseases Use of leech therapy individually in the control group or other complementary medicine methods in both groups

Age
From **60 years** old to **74 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples are placed in two groups of intervention and control group using random blocks (4). The method of assigning 80 samples to the two groups of intervention and control will be such that considering gender (male_woman) and body mass index (normal category and overweight category) as a class, the method of 4 random blocks for Assigning patients to two groups A (intervention) and group B (control) will be used. The normal category is the body mass index (18.5_25) and the overweight category (25_30). To do this, in older men and women, first a list of blocks will be written and numbers will be assigned to them. - ABAB (2) -ABBA (3) - BBAA (4) - BABA (5) - BAAB (6)) Then using a table of random numbers and randomly select numbers between 1 to 6 and finally the list of treatment assignments based on A sequence of letters A and B will be formed. Depending on the type of intervention and the awareness of the samples of the intervention they receive, blinding is not possible in the participants. But to reduce bias, we will try not to let the data collector and statistical analyst know which information belongs to which group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study has an intervention group and a control group for comparison

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Lorestan University of Medical Sciences

Street address
Vice Chancellor for Research and Technology, Lorestan, Khorramabad, Road, Pardis University Complex University of Medical Sciences

City
Khorramabad

Province
Lorestan

Postal code
6813833946

Approval date
2021-09-04, 1400/06/13

Ethics committee reference number
IR.LUMS.REC.1400.127

Health conditions studied

1

Description of health condition studied
osteoarthritis

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Knee pain score
Timepoint
At the beginning of the study (before the intervention) and 7, 14 and 28 days after the intervention
Method of measurement
Osteoarthritis Index of the University of Western Ontario and McMaster

2

Description
Joint dryness score
Timepoint
At the beginning of the study (before the intervention) and 7, 14 and 28 days after the intervention
Method of measurement
Osteoarthritis Index of the University of Western Ontario and McMaster

3

Description
Daily performance score
Timepoint
At the beginning of the study (before the intervention) and 7, 14 and 28 days after the intervention
Method of measurement
Osteoarthritis Index of the University of Western Ontario and McMaster

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to routine treatment, a 30-minute leech therapy session using 6 to 8 medical leeches (sankumukhi type) in a clean, secluded room while maintaining patient privacy and following all coronavirus protection protocols in a traditional medicine clinic environment will be done.Also continue your treatment routine during the intervention
Category
Rehabilitation

2

Description
Control group: They will receive routine treatment and will not receive any intervention from the researcher and will be considered for comparison with the intervention group.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Orthopedic office
Full name of responsible person
Mandana Saki
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Falahi Ebrahim
Street address
Vice Chancellor for Research and Technology, Lorestan, Khorramabad, Road, Pardis University Complex University of Medical Sciences
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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
Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Saki Mandana

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Position

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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 potential data is released after unidentifiable individuals in the form of original message information

When the data will become available and for how long

The access period will start from 2021

To whom data/document is available

Based on evidence-based medicine, if it is effective in improving the symptoms in patients with osteoarthritis of the knee, this method can be used in the clinical environment and in order to strengthen the results of previous research, we will do this research..All researchers, teachers, and medical students can

download the published article from the relevant journal.

Under which criteria data/document could be used

Unidentifiable data will be made available to health researchers for the study of meta-analysis.

From where data/document is obtainable

Send email to Mandana Saki m.saki@modares.ac.ir

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

After sending the documents by the applicant researcher via email,the data will be sent two weeks later

Comments