Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of topical tumeric (Domestica Val. Curcuma) and Serrapeptase on reducing pain and improve range of motion in patients with osteoarthritis of the knee (a double blind randomized controlled trial)

Protocol summary

Study aim

Determining the effect of topical turmeric (Domestica Val. Curcuma) and Serrapeptase in reducing pain, improving range of motion and reducing joint stifness in patients with knee osteoarthritis compared to controls

Design

80 participants (no=40 per group) are randomly assigned to intervention and placebo group using random digit table, trial phase 3

Settings and conduct

This double blinded study will be performed in Fayazbakhsh hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age>45y and having knee osteoarthritis according to American College of Rheumatology diagnostic criteria Knee pain with at least three of the followings: age>50, morning stiffness<30 min, crepitation, bone tenderness at knee, knee bone enlargement, warmness or pain in addition to osteophyte according to radiography Grade 2 or 3 of osteoarthritis according to Kellgren and Lawrence system Pain intensity between 5-8 at baseline according to VAS Able to walk independently Exclusion criteria: not having joint arteritis, orthopedic or severe cardiovascular diseases intra-articular injection of corticosteroids in past 3 months, as well as gel, and PRP in past year Severe pain or allergic reaction during intervention that need for NSAIDs unable to complete the study BMI>35

Intervention groups

After determining pain intensity using VAS and range of motion and stiffness using WOMAC, patients will receive topical serapeptase and turmeric or placebo every 4h for 10 days. Each. VAS and WOMAC will check again after 10 days

Main outcome variables

Main output: effect of turmeric/serapeltase on pain, range of motion and stiffness of patients with knee osteoarthritis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140804018677N7**
Registration date: **2021-02-26, 1399/12/08**
Registration timing: **prospective**

Last update: **2021-02-26, 1399/12/08**
Update count: **0**

Registration date

2021-02-26, 1399/12/08

Registrant information

Name

soodeh razeghi Jahromi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8500

Email address

razeghi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-28, 1399/12/10

Expected recruitment end date

2021-07-01, 1400/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of topical tumeric (Domestica Val. Curcuma) and Serrapeptase on reducing pain and improve range of motion in patients with osteoarthritis of the knee (a double blind randomized controlled trial)

Public title

Effects of tumeric and Serrapeptase gel on reducing pain and improve range of motion in patients with osteoarthritis of the knee

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age>45y and having knee osteoarthritis according to American College of Rheumatology diagnostic criteria Knee pain with at least three of the followings: age>50, morning stiffness<30 min, crepitation, bone tenderness at knee, knee bone enlargement, warmness or pain in addition to osteophyte according to radiography Grade 2 or 3 of osteoarthritis according to Kellgren and Lawrence system Pain intensity between 5-8 at baseline according to VAS Able to walk independently

Exclusion criteria:

having joint arteritis, orthopedic or severe cardiovascular diseases having intra-articular injection of corticosteroids in past 3 months, as well as gel, and Platelet-rich plasma (PRP) in past year having allergic reaction to tumeric and Serrapeptase

Age

From **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will have equal chance to be assigned to studied groups. We will use random digits table to make random sequence. After determining the first number, we will continue downward and allocate even numbers to cases and odd numbers to placebo. As in small sample sizes, it would be probable that one group be completed earlier, if one group completed earlier, we will allocate the other assigned numbers to other group. A person out of study group will put her figure on one digit of the table with closed eyes and according to assumed agreement will go downward through the table and write the numbers down until completing the sample size in each group. Code "A" will allocated to even numbers and considered as "intervention group" and code "B" will allocated to odd numbers and considered as "placebo group". At the end we will have the sequence of 80 specific numbers and A&B codes. A person out of study team will put the numbers in sealed packets till the time of sampling

Blinding (investigator's opinion)

Double blinded

Blinding description

A third person out of study team have the sequence of codes that provide the team with sealed pockets containing allocation code at the time of sampling

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of research and technology deputy of Shahid Beheshti University of Medical Sciences

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2021-02-08, 1399/11/20

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.1030

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
Pain
Timepoint
Baseline and at the end of the study
Method of measurement
VAS (visual analog scale)

2

Description
Range of Motion and stiffness
Timepoint
Baseline and at the end of the study
Method of measurement
WOMAC

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will be asked to gently rub a thin layer of gel containing 0.3% serapeptase and 0.3% bromolin every 4 hours for 10 days.
Category
Treatment - Other

2

Description
Control group: Patients will be asked to gently rub a thin layer of gel containing Triethanolamine every 4 hours for 10 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Fayaz Bakhsh Hospital
Full name of responsible person
Soodeh Razeghi Jahromi
Street address
No. 46, West Arghavan St., Farahzadi Blv., Qods Town
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Tehran
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Postal code
1981619573
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+98 21 2235 7483
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soodehrazeghi@gmail.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
No. 46, West Arghavan St., Farahzadi Blv., Qods Town
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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
Soodeh Razeghi Jahromi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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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

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 would be available to public

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

To all

Under which criteria data/document could be used

No other criteria

From where data/document is obtainable

Email to soodehrazeghi@gmail.com

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

sending email

Comments