

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 stiffness 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 serrapeptase 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/serrapeptase 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

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Email

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

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Email

soodehrazeghi@gmail.com

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

Street address

No. 46, West Arghavan St., Farahzadi Blv., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619537

Phone

+98 21 2235 7483

Email

soodehrazeghi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soodeh Razghei Jahromi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No. 46, West Arghavan St., Farahzadi Blv., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619537

Phone

+98 21 2235 7483

Email

soodehrazeghi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soodeh Razghei Jahromi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No. 46, West Arghavan St., Farahzadi Blv., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619537

Phone

+98 21 2235 7483

Email

soodehrazeghi@gmail.com

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