Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of tumeric (Curcuma longa) and Serrapeptase supplementation 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 oral 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

Settings and conduct
This double blinded study will be performed in Fayaz Bakhsh Hospital. At base line and after 10 days of intervention with supplement/placebo, pain intensity using VAS and range of motion & stiffness using Western Ontario and McMaster Universities Arthritis Index (WOMAC) will be recorded.

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 (Visual Analog Scale) 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 Platelet-rich plasma (PRP) in past year Severe pain or allergic reaction during intervention that need for NSAIDs unable to complete the study Body mass index>35

Intervention groups
Patients will receive serapeptase and turmeric capsule or placebo BD for 10 days. Each capsule contains 30 mg serapeptase and 20 mg turmeric or maltodextrine in placebo group.

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: **IRCT20140804018677N8**
Registration date: **2021-03-02, 1399/12/12**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-02, 1399/12/12**
Update count: **0**

Registration date
2021-03-02, 1399/12/12

Registrant information

Name
soodeh razeghi Jahromi

Name of organization / entity
Tehran University of Medical Sciences

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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 tumeric (Curcuma longa) and Serrapeptase supplementation 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 capsule 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 Visual analog scale-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 Platelet-rich plasma (PRP) in past year Severe pain or allergic reaction during intervention that need for Nonsteroidal anti-inflammatory drugs (NSAIDs) unable to complete the study BMI>35

Age

From **45 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

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

It is a double blind study. 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. The following groups of people involved in the trial: participants, Research team including principle investigator, data collectors, and outcome assessors will be blind.

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.1399.1029

Health conditions studied

1

Description of health condition studied

knee 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

Western Ontario and McMaster Universities Arthritis Index (WOMAC)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Serapeptase (30 mg)/turmeric (20 mg) per cap- for 10 days- rayan pharmed company

Category

Treatment - Other

2

Description

Control group: placebo containing maltodextrine-for 10 days- rayan pharmed company

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Fayaz Bakhsh Hospital

Full name of responsible person

Soodeh Razeghi Jahromi

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Afshin Zarghi

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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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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 critaria
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