Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of N and placebo on knee pain and function in patients with knee osteoarthritis

Protocol summary

Study aim
Investigate of the effect of N-compound subectance on knee pain and function in patients with knee osteoarthritis

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2-3, performed on 25 patients. Excel software was used for randomization.

Settings and conduct
The study site is the rheumatology clinic of Ali-Ibn Abi-Taleb Hospital in Rafsanjan. The study population includes patients with osteoarthritis of the knee referred to the mentioned rheumatology clinic. In this double-blind study, the drug in both groups is the same in color and shape and is prepared in the laboratory by an expert. The container containing oil is filled with one of the two intervention substances or placebo and then is coded. Only the coder who does not participate in the study knows the relevant code, and the analysis is done by another person. In this method, the researcher and the treatment staff of those who communicate with the patients do not know the type of intervention or treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age of 45-70 years old; Non-inclusion criteria: underlying diseases; Hypersensitivity to herbal medicines; smoking

Intervention groups
The control group: The placebo (paraffin, a substance with a similar shape, taste, and smell as intervention drug) is used for two months. Intervention group: Composite substance (olive oil - turmeric - coriander oil and egg yolk), which are received by a physician and it is recommended to massage the drug on the knee for 3 to 5 minutes daily.

Main outcome variables
Inflammation; knee pain

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20210413050959N2**
Registration date: **2021-10-15, 1400/07/23**
Registration timing: **prospective**

Last update: **2021-10-15, 1400/07/23**
Update count: **0**

Registration date
2021-10-15, 1400/07/23

Registrant information

Name
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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2022-01-21, 1400/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effect of N and placebo on knee pain and function in patients with knee osteoarthritis

Public title

The effect of the N compound in the treatment of knee pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

45-70 years old Confirmation of the disease by a rheumatologist according to the criteria of the American College of Rheumatology

Exclusion criteria:

Inflammatory disease Disease the heart Liver disease Kidney disease Allergy to herbal medicines Smoking Drug use Painkillers uses supplements and medicines uses Daily painkillers uses

Age

From **45 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Care provider
- Investigator

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

In random allocation, in order to select individuals and assign them to the two groups of control and intervention, three steps of access sampling, class allocation, and simple random allocation are respectively performed. To do this, first, people with osteoarthritis referred to the clinic and met the inclusion criteria are selected by available sampling. Since, in some cases, despite the application of stochastic programming, there is the possibility of heterogeneity in some initial features in the groups, the effective variables are excluded using the classification method. In this study, age and sex are very important factors in observing education; thus, to ensure the equal distribution of the two variables in the control and intervention groups, people with entry criteria are divided into four, men, women and 50 >, <50 years based on gender and age . Then, the samples divided into each class by a simple randomization method using the Randomization.com website, available to researchers for free, fall into intervention and control groups. For example, in women with age >50, a list of random sequences such as the following is generated, and then, people are divided into two groups of intervention and control based on their number. 1.
b_____ 2.
a_____ 3.
a_____ 4.
b_____ 5.
b_____ 6.
b_____ 7.
a_____ 8.
b_____ 9.
b_____ 10.
a_____ 11.
b_____ 12.
a_____ 13.
a_____ 14.
a_____ 15.
a_____ 16.
b_____

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug used in both groups is the same in color and shape and is prepared in the laboratory by an expert. The container containing oil is filled with one of the two intervention substances or placebo and then is coded. Only the coder who does not participate in the study is aware of the attribution of the code to the intervention or placebo (usually a non-specific substance with a real medicinal shape, taste, and smell); the analysis is performed by another person. The medical staff of those who are somehow related to the samples do not know the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

The compound is made of olive oil, turmeric, coriander oil, and egg yolk. A study with these materials in combination is unprecedented.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Rafsanjan University of Medical Sciences; Imam Ali Boulevard

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Rafsanjan

Province

Kerman

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Approval date

2021-07-10, 1400/04/19

Ethics committee reference number

IR.RUMS.REC.1400.056

Health conditions studied

1

Description of health condition studied
Rheumatoid Arthritis
ICD-10 code
M06.9
ICD-10 code description
Rheumatoid arthritis, unspecified

Primary outcomes

1

Description
knee pain
Timepoint
before intervention and after intervention
Method of measurement
Visual Analogue Scale (VAS) and WOMAC (Western Ontario and Mc Master) questionnaire

2

Description
the joints morning stiffness
Timepoint
before intervention and after intervention
Method of measurement
Visual Analogue Scale (VAS) and WOMAC (Western Ontario and Mc Master) questionnaire

3

Description
the Knee range of motion
Timepoint
before intervention and after intervention
Method of measurement
Visual Analogue Scale (VAS) and WOMAC (Western Ontario and Mc Master) questionnaire

4

Description
the Knee function
Timepoint
before intervention and after intervention
Method of measurement
Visual Analogue Scale (VAS) and WOMAC (Western Ontario and Mc Master) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: N oil compound; The compound is made of olive oil, turmeric, coriander oil, and egg yolk by a traditional medicine pharmacist in Mashhad's Bouali laboratory, which is applied to the knee for 3 to 5 minutes daily.
Category
Treatment - Drugs

2

Description
Control group: The placebo (paraffin oil with a bright yellow pigment, similar to substance N) is synthesized by a traditional medicine pharmacist in the laboratory of Bouali Mashhad, who applies this drug to the knee for 3 to 5 minutes daily.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rheumatology clinic of Rafsanjan
Full name of responsible person
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1

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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
Rafsanjan 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available