Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparing the effect of topical application of Alpinia galanga (Qost) Oil and Diclofenac jel on symptoms of knee osteoarthritis

Protocol summary

Study aim
Determining and comparing the effect of topical application of Alpinia galanga oil with Diclofenac topical gel on joint pain due to knee osteoarthritis

Design
Randomized clinical trial with control group, with parallel groups, triple blind, randomized on 158 patients. Random sequences will be performed as quadruple blocks using statistical software.

Settings and conduct
The place of the study will be health centers is Sabzevar. The study will be double blind in which drug packages are quite similar in shape and the patient and the executor of the design and analyzer are not aware of the contents of the packages.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 45 to 70 years; Patients with osteoarthritis; Written consent to participate in the study; Possibility of taking medicines on time. Non-Inclusion criteria: Patients with abnormal knee anatomy; joint replacement surgery; knee joint infections; serious underlying diseases; severe skin problems of the knee area; intra-articular injection of steroids within the last three months; intramuscular injection of steroids within the last month; known intolerance or allergy to diclofenac or Alpinia galanga oil.

Intervention groups
Intervention group: 5 to 10 drops of Alpinia galanga oil (made by Tehran School of Pharmacy), twice a day for 28 days, topically on the painful joint. Control group: diclofenac gel (product of Behozan Pharmaceutical Company), twice a day for 28 days, topically on the painful joint.

Main outcome variables
Pain; joint function; joint stiffness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200701047978N1**
Registration date: **2020-08-16, 1399/05/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-16, 1399/05/26**
Update count: **0**

Registration date
2020-08-16, 1399/05/26

Registrant information
Name
Samaneh Sadat Asadi
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-04, 1399/05/14

Expected recruitment end date
2020-09-19, 1399/06/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of topical application of Alpinia galanga (Qost) Oil and Diclofenac jel on symptoms of knee osteoarthritis

Public title
The effect of Alpinia galanga oil on reducing the symptoms of knee osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 45 to 70 years old Patients with osteoarthritis according to the American College of Rheumatology Criteria and grade 1 to 3 osteoarthritis according to the Clagren-Lawrence criterion Written consent to enter the study Patient cooperation during the study Possibility of timely and correct use of medicine
Exclusion criteria:
Patients with abnormal knee anatomy and joint replacement surgery Patients with knee joint infections Suffering from serious underlying diseases such as liver and kidney disorders, diabetes, etc. Patients with severe skin problems of the knee area Patients with intra-articular injection of steroids within the last three months prior to enrollment Patients with intramuscular steroid injections within the past month before enrollment Patients with known intolerance or allergy to Diclofenac or Alpinia Galanga Blindness and deafness or inability to communicate Taking psychotropic drugs Taking drugs or taking corticosteroids
Age
From **45 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **158**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple, block randomization method will be used for randomization. The individual randomization unit and the randomization tool are sealed drug packages that are completely similar in shape and the patient and the project operator are not aware of the contents of the packages. The allocation of samples in the study will be based on a random sequence provided by the statistical consultant using statistical software.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Both painkillers are placed in boxes A (Alpinia Galanga) and B (Diclofenac Jel). Samples are treated with medication packages pre-determined by the study supervisor (supervisor). The drug packages are quite similar in shape and the patient and the executor of the plan are not aware of the contents of the packages. In addition, collecting information, assessing patients and completing forms is done by the project manager and his assistant who are not aware of the contents of the packages. Data analysis is also done by the statistician of the project consultant and the project manager who are not aware of the contents of the drug packages.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Sabzevar University of Medical Sciences
Street address
Headquarters of Sabzevar University of Medical Sciences; Asadabadi street
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617213112
Approval date
2020-02-22, 1398/12/03
Ethics committee reference number
IR.MEDSAB.REC.1398.124

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
Before the intervention, after 14 and 28 days after the use of Alpinia galanga Oil and diclofenac gel
Method of measurement
WOMAC standard questionnaire

2

Description

Physical function

Timepoint

Before the intervention, after 14 and 28 days after the use of Alpinia galanga Oil and diclofenac gel

Method of measurement

WOMAC standard questionnaire

3

Description

Joint dryness

Timepoint

Before the intervention, after 14 and 28 days after the use of Alpinia galanga Oil and diclofenac gel

Method of measurement

WOMAC standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Alpinia galanga Oil 5 to 10 drops (amount of active ingredient equal to 80% in sesame oil base made by Tehran School of Pharmacy), twice a day for 28 days topically on the painful joint

Category

Treatment - Drugs

2

Description

Control group: Diclofenac gel (topical gel 1% 60 g product of Behozan Pharmaceutical Company) twice a day for 28 days topically on the painful joint

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzevar health centers

Full name of responsible person

Fereshteh Ghorat

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Headquarters of Sabzevar University of Medical Sciences; Asadabadi street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Fereshteh Ghorat

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work
Traditional Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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Samaneh Sadat Asadi

Position
Medical student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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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