Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of a topical formulation of Trachyspermum ammi fruit essential oil efficacy in reducing chronic arthritic pains (a 2A phase clinical study)

Protocol summary

Study aim
Objective: To evaluate the effect of topical formulation of Trachyspermum ammis fruit essential oil on the reduction of chronic pain of joints and its comparison with conventional medicine

Design
Clinical trial in phase 2, with control group, Parallel, Non-blind, Non-randomized with 20 samples in each group

Settings and conduct
The study is conducted in Ahmadieh clinic, on patients referred to the center

Participants/Inclusion and exclusion criteria
Age over 60, suffering from osteoarthritis in knee, not having severe pain, Lack of history of related surgery, lack of cancer and significant signs of psychiatric disorders, non-use of narcotics, lack of severe chronic disease, no analgesic injection into the knee joint, in 30 days before or during the intervention period.

Intervention groups
1- Group one: Recieving Ajwain Topical gel and Diclofenac topical gel to be aaplied on the pain area, with 15 min interval, for 1 month 2- Group two: Receiving Diclofenac topical gel to be aaplied on the pain area, for 1 month

Main outcome variables
Pain severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160306026938N6**
Registration date: **2018-10-07, 1397/07/15**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-07, 1397/07/15**
Update count: **0**

Registration date
2018-10-07, 1397/07/15

Registrant information

Name
Mahdi Vazirian

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 6412 1223

Email address
vazirian_m@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-07, 1397/07/15

Expected recruitment end date
2018-12-06, 1397/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of a topical formulation of Trachyspermum ammi fruit essential oil efficacy in reducing chronic arthritic pains (a 2A phase clinical study)

Public title
Evaluation of the effect of ajwain topical formulation in reducing chronic joint pains

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent for taking part in the study Age between 60-80 years old Suffering from osteoarthritis pain in one or both knees Having an acceptable cognitive ability based on a short cognitive test (AMT)

Exclusion criteria:

Having severe pain, Visual Analogue Scale (VAS) more than 90 History of any surgery related to this disease on the intended joint Cancer (current or any time before) and obvious symptoms of neuropsychiatric disorders Chronic use of opiates Sever chronic diseases, such as insulin-dependent diabetes Injection of analgesic within the joint in 30 days before the intervention or any programe for injection until the end of the intervention period

Age

From **60 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Siences

Street address

Tehran University of Medical Sciences, Qods street corner, Keshavarz Blvd, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-02-05, 1396/11/16

Ethics committee reference number

IR.TUMS.PSRC.REC.1396.4447

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M15.0

ICD-10 code description

Primary generalized (osteo)arthritis

Primary outcomes

1

Description

Pain through visual and Likert measurements

Timepoint

At the beginning of the study (before the intervention), one week and one month after commencement of topical use of Trachyspermum ammi.

Method of measurement

Ontario and Master Osteoarthritis Index and KOOS (knee osteoarthritis outcome) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Ajwain essential oil (one percent) in topical formulation, will applied in pain area, two times a day alongside Diclofenac gel for one month

Category

Treatment - Drugs

2

Description

Diclofenac gel will applied in pain area, two times a day, for one month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of traditional medicine, Tehran university of medical sciences

Full name of responsible person

Dr. Mehrdad Karimi

Street address

No. 27, North Sarparast Ave. West Taleghani Ave,

Palestine Square
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 6697 6527
Email
vazirian_m@tums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice-chancellor of research and technology, Tehran university of medical sciences
Street address
Central organization of Tehran university of medical sciences, corner of Ghods Ave., Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3619
Email
rmo@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr.Mahdi Vazirian
Position
PhD of Pharmacognosy
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Pharmacognosy Lab., Second Floor, New buliding, Faculty of Pharmacy, In front of Oruji Alley, 16th Azar Ave., Enqelab Ave.
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 6412 1223
Email
Vazirian_m@tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mahdi Vazirian
Position
PhD of Pharmacognosy
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Other areas of specialty/work
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Person responsible for updating data

Contact
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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Data would be accessible in related dissertation
When the data will become available and for how long
The onset of access from 2020
To whom data/document is available
All the people
Under which criteria data/document could be used
The documents could be accessible in case of furthur experiments
From where data/document is obtainable
Iran, Tehran, Tehran University of Medical Sciences, Faculty of Pharmacy, Dr. Mahdi Vazirian
What processes are involved for a request to access data/document
Personal request
Comments