

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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 ammi 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 Ahmadih 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: Receiving Ajwain Topical gel and Diclofenac topical gel to be applied on the pain area, with 15 min interval, for 1 month 2- Group two: Receiving Diclofenac topical gel to be applied 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 programme 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 Sciences

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**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

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

Palestine Square
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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
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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

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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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