

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of Topical Application of Thymus daenensis Celak Extract Gel vs Diclofenac Gel in Knee Osteoarthritis

Protocol summary

Summary

The aim of this study is to investigate the effects of Thymus daenensis gel 5% and diclofenac gel 1% in pain of patients with knee osteoarthritis. This study is a double blind clinical trial, placebo-controlled, single-center is 120 patients with osteoarthritis referring to the Orthopedic Clinic in Shahrekord with Inclusion criteria: 45_75 years old; a definitive diagnosis of osteoarthritis disease with specialist Exclusion criteria: severe diseases such as metabolic disorders and digestive at the same time; severe infection, sensitivity to thyme extract daenensis, pregnancy, lactation, impaired liver function tests; history of fracture or knee surgery; rheumatoid arthritis are randomly select ,divide into three groups of 40 people. The first group receive placebo gel three times a day, the second group of thyme 5% topical gel three times daily and in the third group diclofenac topical gel 1% three times a day. All three groups use celecoxib 200 mg for oral. WOMAC and VAS questionnaires are checked at baseline and six weeks after treatment. Improving Physical symptoms and pain relief are considered as treatment response.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112231025N1**
Registration date: **2017-01-20, 1395/11/01**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-01-20, 1395/11/01

Registrant information

Name

Elena Khalesi

Name of organization / entity

Shahrekord University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Topical Application of Thymus daenensis Celak Extract Gel vs Diclofenac Gel in Knee Osteoarthritis

Public title

Thyme gel in reducing knee pain due to Arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 45_75 years old; a definitive diagnosis of osteoarthritis disease with specialist Exclusion criteria: severe diseases such as metabolic disorders and digestive at the same time; severe infection, sensitivity to thyme extract daenensis, pregnancy, lactation, impaired liver function tests; history of fracture or knee surgery; rheumatoid arthritis

Age
From **45 years** old to **75 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Shahrekord, Shahrekord University of Medical Sciences

City

Shahrekord

Postal code

Approval date

2016-05-29, 1395/03/09

Ethics committee reference number

IR.SKUMS.REC.1395.54

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M19.9

ICD-10 code description

Arthrosis, unspecified

Primary outcomes

1

Description

Improving physical Function

Timepoint

Baseline and Six Weeks later

Method of measurement

WOMAC questionnaire

Secondary outcomes

1

Description

Pain relief

Timepoint

Baseline and Six Weeks later

Method of measurement

VAS questionnaire

Intervention groups

1

Description

The first group received placebo gel topically 3 times a day with 200 mg celecoxib capsules for oral use

Category

Treatment - Drugs

2

Description

The Second group received Thymus daenensis extract gel 5% gel topically 3 times a day with 200 mg celecoxib capsules for oral use

Category

Treatment - Drugs

3

Description

The Third group received diclofenac gel 1% gel topically 3 times a day with 200 mg celecoxib capsules for oral use

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital in Shahrekord

Full name of responsible person

Morteza Dhghan

Street address

Shahrekord, Shahrekord University Of Medical Sciences

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shahrekord University of Medical Science

Full name of responsible person

Dr. Kamal Solati

Street address

Shahrekord, Shahrekord University of Medical Sciences

City

Shahrekord

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research of Shahrekord University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Shahrekord University of Medical Sciences

Full name of responsible person

Morteza Dehghan

Position

Associate Professor, Orthopedic specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty