Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the effect of topical 1% Hedera helix L. extract gel with 1% Diclofenac gel in the treatment of patients with primary knee osteoarthritis referred to orthopedic clinic

Protocol summary

Summary

The aim of this study is to compare the analgesic effect of 1% Hedera helix extract gel with 1% Diclofenac gel on knee pain in osteoarthritis patients. It is a double blind randomized clinical trial. The 1% Hedera helix extract, 1% Diclofenac gel and placebo gel will all be set in A,B, and C tubes by a trustworthy third party and will be handed over to the researcher. 150 patients seeking medical care in orthopedic clinics will randomly receive one of the tubes. The main inclusion criteria is primary osteoarthritis in at least one knee confirmed radiologicaly in the knee plain x-ray, presence of pain for at least 2 weeks before the visit and age of 45 years and older. The main exclusion criteria is secondary osteoarthritis, peptic ulcer, taking corticosteroids for any reason, and using any analgesic topical gel on the knee before the study. Before receiving the gel, patient pain will be assessed using VAS and WOMAC questionnaires. Patients will rub the gel on the affected knee for 6 weeks three times a day, each time for 15-20 minutes. All three groups will receive 200 mg Celecoxib capsules simultaneously to subside the pain. After 6 weeks of administration, patients pain, morning stiffness, daytime stiffness and physical function will be assessed again by VAS and WOMAC.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050133740N1**
Registration date: **2017-09-26, 1396/07/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-09-26, 1396/07/04

Registrant information

Name
Mahdie Saffari
Name of organization / entity
Shahrekord University of Medical sciences
Country
Iran (Islamic Republic of)
Phone
+98 913 410 4240
Email address
st-saffari.m@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research center of Shahrekord University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of topical 1% Hedera helix L. extract gel with 1% Diclofenac gel in the treatment of patients with primary knee osteoarthritis referred to orthopedic clinic

Public title

Comparing the effect of topical 1% Avy extract gel with 1% Diclofenac gel in the treatment of patients with

primary knee osteoarthritis referred to orthopedic clinic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Primary osteoarthritis in at least one knee confirmed radiologicaly on a knee x-ray; Pain presence from at least 2 weeks prior to visit; Age> 45. Exclusion criteria: Secondary osteoarthritis; Active liver or kidney disease; Peptic ulcer disease; Diabetes; Thyroid or parathyroid diseases; Coagulopathy or taking anti-coagulatory drugs; Ischemic or hemorrhagic CVA; Past history of deep vein thrombosis; Allergy to any form of anti-inflammatory agents, Acute trauma; Alcohol use; Drug abuse; Skin diseases, infection or wound on the site of the study; Corticosteroid use in any form; Using other topical agents on the site of the study; Taking oral agents effective on osteoarthritis within 10 days from the start of the study; Pregnancy; History of the site fracture; Deformities leading to osteoarthritis; Congenital joint diseases.

Age

From **45 years** old to **139 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

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

Research center of Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences, Kashani Blv.

City

Shahrekord

Postal code

Approval date

2017-02-19, 1395/12/01

Ethics committee reference number

IR.SKUMS.REC.1395.40

Health conditions studied

1

Description of health condition studied

Gonarthrosis

ICD-10 code

M17.1l

ICD-10 code description

Other primary gonarthrosis Primary gonarthrosis: NOS unilatera

Primary outcomes

1

Description

Pain

Timepoint

Before and after intervention

Method of measurement

VAS and WOMAC questionnaires

2

Description

Morning stiffnes

Timepoint

Before and after intervention

Method of measurement

VAS and WOMAC questionnaires

3

Description

Stiffness during the day

Timepoint

Before and after intervention

Method of measurement

VAS and WOMAC questionnaires

4

Description

Physical function

Timepoint

Before and after intervention

Method of measurement

VAS and WOMAC questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

1% Hedera helix extract gel, topical use, three times a day.

Category

Treatment - Drugs

2

Description

1% Diclofenac gel, topical use, three times a day.

Category

Treatment - Drugs

3

Description

Placebo gel, topical use, three times a day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialty clinic of Imam Ali of Shahrekord

Full name of responsible person

Morteza Dehghan MD

Street address

Shariati st.

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research center of Shahrekord University of Medical Sciences

Full name of responsible person

Dr Kamal Solati

Street address

Shahrekord University of Medical Sciences, Kashani Blvd.

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 center of Shahrekord University of Medical Sciences

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

Mahdie Saffari

Position

Medical student

Other areas of specialty/work

Street address

Hajar hospital, Parastar st.

City

Shahrekord

Postal code

Phone

+98 38 3222 0016

Fax

Email

mahdiesaffari@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Morteza Dehghan

Position

Orthopedist

Other areas of specialty/work

Street address

Kashani hospital, Parastar st.

City

Shahrekord

Postal code

Phone

+98 38 3226 4825

Fax

Email

dehghan_morteza@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Mahdie Saffari

Position

Medical student

Other areas of specialty/work

Street address

Hajar hospital, Parastar st.

City

Shahrekord

Postal code

Phone

00

Fax

Email

mahdiesaffari@yahoo.com

Web page address

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