

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Assessment of Sambucus ebulus effect on clinical manifestation of knee Osteoarthritis versus Diclofenac gel :A double blind clinical trial

Protocol summary

2015-03-20, 1393/12/29

Summary

Purpose: Assessment of Sambucus ebulus effect on clinical manifestation of knee Osteoarthritis versus Diclofenac gel :A double blind clinical trial. Study design: This study is a randomized, double-blind, controlled trial. Study population: Patients with primary osteoarthritis in at least one knee, will randomly divide into two groups. Group I (31 patient) receive sambucus ebulus gel 3 times daily, Group II (31 patient) receive Diclofenac gel 3 times daily. All drugs will use in simillar pakage with different code. Inclusion Criteria: age: 30-60 years; A history of knee pain for at least 3 months; Mild to moderate Osteoarthritis based on Kellegren-Lawrence grading scale; Exclusion Criteria: Allergy to Sambucus ebulus & Diclofenac gel; Skin lesions in the knee; Osteoarthritis secondary to Rheumatic disease such as Rheumatoid Arthritis, Gout, Infectious Arthritis, Metabolic Arthritis, Traumatic Arthritis; Knee joint replacement surgery; Oral and topical steroid therapy within 14 days prior to study; Intra-articular steroid injections within 90 days prior to study; Pregnancy and lactation; Addiction to alcohol and drugs; Radiculopathy and Neuropathy. Time of interventions: The patients will be assessed at initiation, 2 and 4 weeks after the intervention, using the WOMAC and VAS questionnaire. Main outcome: Pain, stiffness and physical function

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080318494N1**
Registration date: **2015-03-20, 1393/12/29**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Marzie Jabbari

Name of organization / entity

Ardakan Traditional Medicine Faculty, Yazd Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 2723 8916

Email address

marzie.jabbari@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Shahid Sadougehi University of Medical Sciences

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Sambucus ebulus effect on clinical manifestation of knee Osteoarthritis versus Diclofenac gel :A double blind clinical trial

Public title

Sambucus ebulus effect on knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: age: 30-60 years; A history of knee pain for at least 3 months; Mild to moderate Osteoarthritis (grade 1 and 2) based on Kellegren-Lawrence grading scale; Exclusion Criteria: 1-Allergy to Sambucus ebulus & Diclofenac gel; Skin lesions in the knee; Osteoarthritis secondary to Rheumatic disease such as Rheumatoid Arthritis, Gout, Infectious Arthritis, Metabolic Arthritis, Traumatic Arthritis; Knee joint replacement surgery; Oral and topical steroid therapy within 14 days prior to study; Intra-articular steroid injections within 90 days prior to study; Pregnancy and Lactation; Addiction to alcohol and drugs; Radiculopathy and Neuropathy

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee, Yazd Shahid Sadougei Univesity of Medical Sciences

Street address

Central department of Shahid Sadougei Medical University, Shahid bahonar squer, Yazd

City

Yazd

Postal code

8916978477

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

17/1/65403/پ

Health conditions studied**1****Description of health condition studied**

knee osteoarthritis

ICD-10 code

M19.0

ICD-10 code description

Primary arthrosis of other joints

Primary outcomes**1****Description**

Pain

Timepoint

Baseline, 2 and 4 weeks after intervention

Method of measurement

WOMAC questionnaire

2**Description**

Stiffness

Timepoint

Baseline, 2 and 4 weeks after intervention

Method of measurement

WOMAC questionnaire

Secondary outcomes**1****Description**

physical function

Timepoint

Baseline, 2 and 4 weeks after intervention

Method of measurement

WOMAC questionnaire

Intervention groups**1****Description**

Receive topical consumption of sambucus ebulus gel, Every 8 hour on all of site of knee for 30 days

Category

Treatment - Drugs

2**Description**

Receive topical consumption of Diclofenac gel, Every 8 hour on all of site of knee for 30 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Marzie Jabbari

Street address

Brain and Spinal Cord Research Center, Imam Khomeini Hospital, Keshavarz Blvd, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Shahid Sadougehi University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Ezoddini

Street address

Central Building of Shahid Sadougehi Medical University, Shahid Bahonar squer, Yazd

City

Yazd

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, Shahid Sadougehi 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

Traditional Medicine Faculty of Ardakan, Shahid Sadougehi University of Medical Sciences

Full name of responsible person

Marzie Jabbari

Position

PhD candidate

Other areas of specialty/work

Street address

Imam Khomeini ave

City

Ardakan

Postal code

Phone

+98 35 2723 8917

Fax

+98 35 2724 6330

Email

marzie.jabbari@ssu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Imam Khomeini Hospital

Full name of responsible person

Dr seyede Zahra Emami Razavi

Position

Assistant Professor of Physical Medicine and Rehabilitation

Other areas of specialty/work

Street address

Brain and Spinal Cord Research Center, Imam Khomeini Hospital, Tehran

City

Tehran

Postal code

Phone

+98 21 6119 2291

Fax

Email

zemamirazavi@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Imam Khomeini Hospital

Full name of responsible person

Marzie Jabbari

Position

PhD candidate

Other areas of specialty/work

Street address

Brain and Spinal Cord Research Center, Imam Khomeini Hospital, Tehran

City

Tehran

Postal code

Phone

+98 21 6119 2210

Fax

Email

marzie.jabbari@ssu.ac.ir

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