Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

Protocol summary

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 ostheoarthritis 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 and4 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

2015-03-20, 1393/12/29

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Shahid Sadoughei 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 Sadoughei Univesity of Medical Sciences

Street address
Central department of Shahid Sadoughei 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 osteoartritis

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research, Shahid Sadoughei University of Medical Sciences
Full name of responsible person
Dr. Fatemeh Ezoddini
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Central Building of Shahid Sadoughei Medical University, Shahid Bahonar squer,Yazd
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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
Vice Chancellor for research, Shahid Sadoughei 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

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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