Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of Topical 1% Hedera helix L. Extract gel and 1% Diclofenac gel in the Treatment of Primary Knee Osteoarthritis Patients

Protocol summary

Study aim
The aim of this study is to compare the effect of the topical use of 1% Hedera helix L. extract gel and 1%diclofenac gel on knee osteoarthritis.

Design
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct
The study population consisted of 150 patients referring to Imam Ali Clinic affiliated with Shahrekord University of Medical Sciences and private offices across Shahrekord diagnosed with knee osteoarthritis who were selected by convenience sampling.

Participants/Inclusion and exclusion criteria
Inclusion criteria were primary osteoarthritis in at least one knee with orthopedic diagnosis based on radiological criteria in knee image, having pain at least 2 weeks before treatment, and having age above 45 years. People who had secondary osteoarthritis, active liver or kidney disease, peptic ulcer, diabetes, thyroid and parathyroid diseases, and coagulation disorders, consumed anticoagulant drugs, history of ischemic or hemorrhagic stroke or deep vein thrombosis, allergy to any anti-inflammatory drug, alcohol abuse, drug abuse, orally used other analgesics and other effective compounds for the treatment of osteoarthritis up to 10 days before beginning of the study, and had pregnancy, history of local fractures, and deformities leading to osteoarthritis and articular diseases were not enrolled in the study.

Intervention groups
Patients were divided into three groups of 50 each by convenience random allocation, and each group used only one of the tubes of 60 g of diclofenac 1% gel, H. helix extract 1% gel, and placebo. Demographic data were collected and The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and a standard instrument to measure pain, namely, visual analogue scale (VAS) were administered.

Main outcome variables
Knee pain; Morning stiffness; Daytime stiffness; Physical function

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20110514006480N14**
Registration date: **2018-06-08, 1397/03/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-08, 1397/03/18**
Update count: **0**

Registration date
2018-06-08, 1397/03/18

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-05, 1397/03/15

Expected recruitment end date
2018-11-06, 1397/08/15

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 and 1% Diclofenac gel in the Treatment of Primary Knee Osteoarthritis Patients

Public title
Effect of Topical 1% Hedera helix L. Extract gel in Treatment of Primary Knee Osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Primary osteoarthritis in at least one knee Having pain at least 2 weeks before treatment
Exclusion criteria:
Secondary osteoarthritis Active liver or kidney disease, peptic ulcer, diabetes, thyroid and parathyroid diseases, and coagulation disorders Consumed anticoagulant drugs History of ischemic or hemorrhagic stroke or deep vein thrombosis, history of local fractures, and deformities leading to osteoarthritis and articular diseases Allergy to any anti-inflammatory drug Alcohol abuse, drug abuse Used Corticosteroids of any type and other topical drugs at the site where the gel was applied, orally used other analgesics and other effective compounds for the treatment of osteoarthritis up to 10 days before beginning of the study Pregnancy
Age
From **45 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into three groups by simple random sampling and Using three categories of cards that listed on them the letters A, B and C
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study considering the use of similar tubes in all three groups participants and their carers, as well as the assessor, are not aware of the contents of the tubes.
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی شهرکرد
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خیابان آیت الله کاشانی
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۸۸۱۵۷۱۳۴۷۱
Approval date
2016-12-21, 1395/10/01
Ethics committee reference number
IR.SKUMS.REC.1395.40

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis
ICD-10 code
M15-M19
ICD-10 code description
Arthrosis

Primary outcomes

1

Description
Severity of knee pain
Timepoint
Before as well as one, two, three, and six weeks after intervention
Method of measurement
Visual analog scale

2

Description
Morning stiffness
Timepoint
Before as well as one, two, three, and six weeks after intervention
Method of measurement
Western Ontario and McMaster Universities Osteoarthritis Index

3

Description
Daytime stiffness
Timepoint
Before as well as one, two, three, and six weeks after intervention
Method of measurement
Western Ontario and McMaster Universities Osteoarthritis Index

4

Description
Physical function
Timepoint
Before as well as one, two, three, and six weeks after intervention
Method of measurement
Western Ontario and McMaster Universities Osteoarthritis Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: topical use of 1% diclofenac gel (the tubes of 60 gram); three times a day for six weeks and each time applied the gel over the site of interest for 3 to 5 minutes.
Category
Treatment - Drugs

2

Description
Intervention group 2: topical use of 1% H. helix extract 1% gel (the tubes of 60 gram); three times a day for six weeks and each time applied the gel over the site of interest for 3 to 5 minutes.
Category
Treatment - Drugs

3

Description
Control group: topical use of placebo (the tubes of 60 gram); three times a day for six weeks and each time applied the gel over the site of interest for 3 to 5 minutes.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Ali Clinic of Shahrekord
Full name of responsible person
Dr Morteza Dehghan
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
2854
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Morteza Dehghani

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available