Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

comparsion of the effects of 3% Cichorium intybus L. hydroalcoholic extract gel vs diclofenac gel in the treatment of patients with primary monoarticular knee osteoarthritis who are taking celecoxib.

Protocol summary

Study aim
Determine and compare the therapeutic effects of 3% gel of hydroalcoholic extract of Chicory and diclofenac in the treatment of knee joint primary osteoarthritis.

Design
Double-blind randomized clinical trial with parallel and control group

Settings and conduct
This study was performed on 150 patients with knee osteoarthritis referred to the orthopedic clinic. The patients were randomly distributed by selecting a card in one of 3 groups A, B, and C. The groups were identical in terms of age, gender and weight, and the patients and the researcher were unaware of the contents of the gel tubes. After 6 weeks of using the medications, the information was re-collected and compared with other groups and with the information before the start of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age of 40-80 years, weight of 50-810 kgs, primary knee osteoarthritis approved by radiological criteria in knee graphy, secondary osteoarthritis or suspecting to it, lack of liver and kidney disease or any other underlying illness, Not having a history of allergies
Exclusion criteria: Primary osteoarthritis in both knees, Skin diseases or infection or ulcers at the place of topical use of the drug, Use of other topical drugs at the area, The use of aromatase inhibitors, Oral administration of other analgesics and other effective compounds in the treatment of osteoarthritis up to 10 days before the start of the study, Arthralgia, Pregnancy

Intervention groups
Patients were divided into 3 groups receiving diclofenac and hydroalcoholic extract of chicory and placebo gel in addition to receiving celecoxib capsule.

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT2017103037093N1**
Registration date: **2017-11-20, 1396/08/29**
Registration timing: **prospective**

Last update: **2019-04-07, 1398/01/18**
Update count: **1**

Registration date
2017-11-20, 1396/08/29

Registrant information

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Name of organization / entity
Shahrekord University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Shahrekord University of Medical Sciences

Expected recruitment start date
2017-12-03, 1396/09/12

Expected recruitment end date
2018-03-21, 1397/01/01

Actual recruitment start date

2017-12-11, 1396/09/20

Actual recruitment end date

2019-01-10, 1397/10/20

Trial completion date

2019-02-14, 1397/11/25

Scientific title

comparsion of the effects of 3% Cichorium intybus L. hydroalcoholic extract gel vs diclofenac gel in the treatment of patients with primary monoarticular knee osteoarthritis who are taking celecoxib.

Public title

Chicory gel effect on the treatment of osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age of 40-80 years weight of 50-80 kgs primary osteoarthritis in one knee, confirmed by radiological criteria in knee graphy secondary osteoarthritis or suspecting to it lack of history of cognitive impairment lack of Liver,kidney or any other underlying disease having no history of allergies

Exclusion criteria:

primary osteoarthritis in both knees history of allergy to any form of anti-inflammatory drugs skin diseases,infection or ulcers at the site of topical use of the drug use of other topical drugs at the place of use of the drug use of aromatase inhibitors the oral administration of other analgesics and other compounds effective in the treatment of osteoarthritis up to 10 days before the start of the study congenital joint diseases pregnancy lack of cooperation and desire of the individual during the study to continue the company creation of any Sensitivity or any problem during the intervention

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **150**

Actual sample size reached: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was done using random numbers table and statistical software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The gel tubes were prepared by the pharmacist and were labeled A, B, and C. None of the patients and researchers knew about their content.

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

Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713492

Approval date

2017-10-29, 1396/08/07

Ethics committee reference number

IR.SKUMS.REC.1396.154

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

Other primary gonarthrosis

Primary outcomes

1

Description

Knee pain

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Western Ontario & McMaster Universities Osteoarthritis Index & Visual Analogue Scale questionnaire

2

Description

daytime stiffness

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Western Ontario & McMaster Universities Osteoarthritis

Index questionnaire

3

Description
Morning stiffness
Timepoint
Before intervention, 6 weeks after intervention
Method of measurement
Western Ontario & McMaster Universities Osteoarthritis Index questionnaire

4

Description
Physical performance
Timepoint
Before intervention, 6 weeks after intervention
Method of measurement
Western Ontario & McMaster Universities Osteoarthritis Index questionnaire

Secondary outcomes

1

Description
Skin allergy
Timepoint
Six weeks after the intervention
Method of measurement
Observation and examination

Intervention groups

1

Description
Negative control group: Patients with primary monoarticular osteoarthritis of knee joint who take 200 mg celecoxib tablets once a day and use the gel containing the base of the gel (placebo) three times a day each time for 3 to 5 minutes for 6 Weeks over the involved area.
Category
Placebo

2

Description
Positive control group: Patients with primary monoarticular osteoarthritis of knee joint who take 200 mg celecoxib tablets once a day, and use 1% diclofenac gel three times a day each time for 3 to 5 minutes for 6 weeks over the involved area.
Category
Treatment - Drugs

3

Description
Intervention group: Patients with primary monoarticular osteoarthritis of knee joint who take 200 mg celecoxib tablets once a day and use 3% chicory gel three times a day for 3 to 5 minutes for 6 weeks over the involved area.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Orthopedic office
Full name of responsible person
Dr. Morteza Dehghan (Associate Professor of Orthopedics)
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahrekord University of Medical Sciences
Full name of responsible person
Dr. seyed Kamal Solati(Associate Professor of Psychology)
Street address
Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd
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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, Shahrekord 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
Shahrekord University of Medical Sciences

Full name of responsible person
Morteza Dehghan

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not 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
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Information about the main outcome can be shared.

When the data will become available and for how

long

Start the access period 4 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Use data to complete clinical trial studies

From where data/document is obtainable

Kashani Hospital in Shahrekord, dehghan_mortaza@yahoo.com

What processes are involved for a request to access data/document

after the investigation of researcher request and presentation of required documents will be accessible.

Comments