Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

The comparison of the effect of Harpagophytum and Curcuma and diclofenac sodium on pain, stiffness and physical function of knee in elderly patients with osteoarthritis

Protocol summary

Study aim
Evaluation and comparison of the effect of Harpagophytum and Curcuma and diclofenac sodium on pain, stiffness and physical function of knee in elderly patients with osteoarthritis

Design
Randomly using the hexagonal permutation blocks method Double blinded trial Medications are taken orally twice daily during the morning when you wake up and at night when you are asleep for 30 days. Also, in 5 steps at the beginning of the experiment and at one week to one month intervals, the Woemek instrument questionnaire of pain, joint stiffness and knee function was recorded.

Settings and conduct
Traditional medicine center of Sabzevar University of Medical Sciences

Participants/Inclusion and exclusion criteria
Elderly men and women 60 years and over - Knee pain more than two months - Joint stiffness less than 30 minutes morning - Swelling on knee examination - Knee osteoarthritis diagnosed by radiographic evidence - No history of surgery related to the disease (eg replacement and joint repair) On the knee - Acceptable cognitive ability based on a brief cognitive test tool (score of 7 and above) - Ability to communicate and adhere to medication regimen - Injection of the drug into the knee joint within 30 days prior Intervention or program for injection until the end of the study period - Absence of heart disease - Absence of history of gastric ulcer

Intervention groups
Three intervention groups, group one devil's claw (Christine 480 million g tenthal), group two 80 ml sinaccuramine capsule and group three diclofenac sodium 25 guest 2 daily draw.

Main outcome variables
pain, stiffness and physical function of knee

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200107046033N1**
Registration date: **2020-02-23, 1398/12/04**
Registration timing: **prospective**

Last update: **2020-02-23, 1398/12/04**
Update count: **0**

Registration date
2020-02-23, 1398/12/04

Registrant information

Name
Raha Salehabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4465 7265

Email address
rahasalehabadi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-03, 1399/01/15

Expected recruitment end date
2020-09-05, 1399/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of the effect of Harpagophytum and Curcuma and diclofenac sodium on pain, stiffness and physical function of knee in elderly patients with osteoarthritis

Public title
effect of Harpagophytum and Curcuma and diclofenac sodium in elderly patients with osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Knee osteoarthritis diagnosed by radiographic evidence and medical expert Knee pain more than two months Acceptable cognitive ability based on a brief cognitive test tool (score of 7 and above) No history of surgery related to the disease (eg replacement and joint repair) Non-injection of the drug into the knee joint within 30 days prior to intervention or schedule for injection until the end Study period

Exclusion criteria:
Taking narcotic drugs History of gallbladder and liver disease any surgery in the next 2 weeks Blindness and deafness and inability to communicate severe and untreated diseases Use of psychotropic drugs

Age
From **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals who were eligible for the study were randomly assigned to the six-group permutation blog (blocks are multiples of the number of groups) with 6 individuals divided into three groups. Random number tables are used to select the number of blocks. (Permuted block randomization (6 parts)

Blinding (investigator's opinion)
Double blinded

Blinding description
Participant blindness: The drugs in the study are placed in identical containers and provided by the researcher with the help of the participant. Researcher blindness: Benefiting from researcher assistance

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences

Street address
Hemmat5- Adib2- niyayesh

City
Sabzevar

Province
Razavi Khorasan

Postal code
9618755736

Approval date
2020-01-04, 1398/10/14

Ethics committee reference number
IR.MEDSAB.REC.1398.078

Health conditions studied

1

Description of health condition studied
osteoarthritis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain, stiffness and knee joint function based on the WOMAC questionnaire

Timepoint
In 5 steps at the beginning of the experiment and at intervals of one week to one month

Method of measurement
WOMAC questionnaire

Secondary outcomes

1

Description
pain reduction

Timepoint
5 times: 1 before intervention and 4 times after intervention with weekly intervals for 4 weeks

Method of measurement
WOMAC questionnaire

Intervention groups

1

Description
Intervention group 1: 40 mg curcumin tablet administered by Exir Nano Sina Pharmaceutical Company once daily.
Category
Treatment - Drugs

2

Description
Intervention group 2: Talental 480 mg tablet administered by Razak Pharmaceutical Company twice daily.
Category
Treatment - Drugs

3

Description
Intervention group III: 25mg sodium diclofenac tablet administered by Razak Pharmaceutical Company twice daily.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Traditional medicine center .Sabzevar University of Medical Sciences
Full name of responsible person
Fereshte Ghorat
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
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Fereshte Ghorat)Vice-chancellor in Research and Technology, Sabzevar University of Medical Sciences)
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Bojnord University of Medical Sciences
Proportion provided by this source
14
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
Sabzevar University of Medical Sciences
Full name of responsible person
Raha Salehabadi
Position
faculty member
Latest degree
Master
Other areas of specialty/work
Geriatric
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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Information about the results of the study can be published.

When the data will become available and for how long
Data Access: Six months after the article was published

To whom data/document is available
Researchers working in academic and scientific institutions Industry practitioners Traditional medicine centers

Under which criteria data/document could be used
Researchers can provide their clients with a range of seniority and therapies as written research requests with the consent of their international company.

From where data/document is obtainable
After obtaining the written consent of the research team, it is possible to refer or correspond to the Vice President of Research and Technology of Sabzevar University of Medical Sciences.

What processes are involved for a request to access data/document
After obtaining the written consent of the research team, it is possible to refer or correspond to the Vice President of Research and Technology of Sabzevar University of Medical Sciences.

Comments