Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Terminalia chebula gel in reducing the pain of patients with knee osteoarthritis: triple-blind randomized clinical trial

Protocol summary

Study aim

Determining the effect of Black Helilah gel in reducing the pain of patients with knee osteoarthritis

Design

First, after the confirmation of the scientific name, the fruit of the Black Helilah plant is extracted by the maceration method, and the preparation of the gel formulation will be done by a pharmacognosist. In this three-blind clinical trial, after receiving the permission of the ethics committee and informed consent, 78 patients with knee osteoarthritis were selected and randomly divided into 3 groups of 26 people. The first group took placebo gel 3 times a day, the second group took 5% Black Helilah topical gel 3 times a day, and the third group took 1% diclofenac topical gel 3 times a day.

Settings and conduct

Our study population is patients with knee osteoarthritis in the age group of 45-75 years old, referring to the teaching clinic of Shahrekord University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Entry: age range of 45-75 years and definite diagnosis of osteoarthritis based on diagnostic criteria by a specialist doctor Non-entry: absence of simultaneous severe diseases such as metabolic and gastrointestinal diseases, absence of severe infection, absence of pregnancy and breastfeeding and disturbed liver tests, absence of history of old fracture or knee surgery, absence of rheumatoid arthritis and seronegative and seropositive arthropathies, absence of history Intra-articular injection within the last 6 weeks

Intervention groups

78 patients with knee osteoarthritis were selected and randomly divided into 3 groups of 26 people. The first group consumes placebo gel 3 times a day, the second group consumes 5% Black Halila topical gel 3 times a day, and the third group consumes 1% diclofenac topical gel 3 times a day.

Main outcome variables

Reducing knee pain and stiffness and improving quality of life in patients with osteoarthritis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240406061427N1**
Registration date: **2024-07-15, 1403/04/25**
Registration timing: **prospective**

Last update: **2024-07-15, 1403/04/25**
Update count: **0**

Registration date

2024-07-15, 1403/04/25

Registrant information

Name

Navid Oboudiat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 5792

Email address

st_navid@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-22, 1403/05/01

Expected recruitment end date

2024-10-21, 1403/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Terminalia chebula gel in reducing the pain of patients with knee osteoarthritis: triple-blind randomized clinical trial

Public title
Effect of Terminalia chebula gel in reducing the pain of patients with knee arthritis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with a definite diagnosis of osteoarthritis based on diagnostic criteria by a specialist doctor Age range between 45 and 75 years

Exclusion criteria:
The presence of simultaneous severe diseases such as metabolic and gastrointestinal diseases Severe infection Pregnancy and breastfeeding and abnormal liver tests History of old fracture or knee surgery Rheumatoid arthritis and seronegative and seropositive arthropathy History of intra-articular injection in the last 6 weeks

Age
From **45 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
The random unit The random unit will be an individual participant. Each participant is randomly assigned to one of the two groups of intervention (Black Haliley gel) or control group (placebo gel). Layered randomization In layered randomization, participants are layered based on key variables such as age, gender and primary pain in order to ensure balanced distribution among therapeutic groups. For example, layers are defined by age groups (less than 5 years, 2 years and older), gender (male, female) and primary pain (low, medium, severe). The random sequence of random numbers generated by the computer will be used. This sequence is produced using statistical software such as SPSS, R or SAS to ensure randomness in randomization if the individual is observed, the individual is entered into the intervention group and if the number is even, the control group is entered into the control group. Allocation Concealment: The study coordinator delivers the relevant gel to the participant after completing the initial evaluation of the participant and confirming his or her qualification to participate in the study, and reviewing the allocated treatment group (intervention/ control).

Blinding (investigator's opinion)
Triple blinded

Blinding description
The samples prepared by the pharmacognosist colleague are packed in tubes marked with A, B and C so that the researcher, the patient and the statistician of the project are not aware of the content of the three types of tubes A, B and C.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Medical School of Medical Sciences of Shahrekord University of Medical Sciences

Street address
Kashani street

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8813833435

Approval date
2024-01-03, 1402/10/13

Ethics committee reference number
IR.SKUMS.MED.REC.1402.087

Health conditions studied

1

Description of health condition studied
knee osteoarthritis

ICD-10 code
M19.9

ICD-10 code description
Osteoarthritis, unspecified site

Primary outcomes

1

Description
knee pain

Timepoint
The first, third and the first, third and sixth weeks after the start of the intervention

Method of measurement
Based on VAS and WOMAC Patients' pain is measured

through the VAS (Visual Analogue Scale) questionnaire and their performance through the Womac (Western Ontario and McMaster Universities Index) questionnaires.

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: 26 patients with knee osteoarthritis are selected. The first intervention group consumes 5% Halileh black topical gel 3 times a day locally on the knee. Participants will be informed that the type of treatment they received will not be known to avoid bias. They are also encouraged not to guess which treatment they received during the study.
Category
Treatment - Drugs

2

Description
The second intervention group: 26 patients with knee osteoarthritis are selected. The second intervention group uses diclofenac 1% topical gel 3 times a day.
Category
Treatment - Drugs

3

Description
Control group: 26 patients with knee osteoarthritis are selected. The control group consumes placebo gel 3 times a day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar Shahrekord Hospital
Full name of responsible person
Navid Oboudiat
Street address
Parastar St.
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8816754633
Phone
+98 913 985 4865
Email
nimanimanima@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Elham Reisi
Street address
Kashani St.
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8813833435
Phone
+98 38 3334 9507
Email
navid.1999@yahoo.com
Grant name
Grant code / Reference number
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
Navid Oboudiat
Position
Intern
Latest degree
Bachelor
Other areas of specialty/work
General Practitioner
Street address
Molavi St.
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8179947161
Phone

+98 31 3650 5792

Email

navid.1999@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Navid Oboudiat

Position

Intern

Latest degree

Bachelor

Other areas of specialty/work

General Practitioner

Street address

Molavi St.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8179947161

Phone

+98 31 3650 5792

Email

navid.1999@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Navid Oboudiat

Position

Intern

Latest degree

Bachelor

Other areas of specialty/work

General Practitioner

Street address

Molavi St.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8179947161

Phone

+98 31 3650 5792

Email

navid.1999@yahoo.com

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

Yes - There is a plan to make this available

Title and more details about the data/document

To share the data and documents of this research, only the information related to the main outcome will be shared. Also, files that can be published and do not violate people's privacy will be published.

When the data will become available and for how long

The access period will start 6 months after the results are published.

To whom data/document is available

Our data will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

If there are conditions, all our data will be shared except personal information of people. The use of our data will only be allowed for similar research and review of our data by other researchers. All those who work in universities and scientific centers and decide to conduct similar research or check the accuracy of our data can access our data.

From where data/document is obtainable

In order to receive information, all eligible people can collect data by referring to the person in charge of the project. The contact methods are the email address navid.1999@yahoo.com or the contact number 00989103259963.

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

To receive information after sending the request, the requests will be reviewed within 10 days. If the above conditions are met, the information will be sent to the provided email within 30 days at most.

Comments