Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Effect of local cannabinoid administration on knee osteoarthritis: A randomized triple-blind placebo based clinical trial

Protocol summary

Study aim
Effect of local cannabinoid administration on knee osteoarthritis: A randomized triple-blind placebo based clinical trial

Design
Clinical trial with placebo group, with parallel groups, three blinded, randomized, phase 2-3 on 50 patients. Random allocation software was used for randomization.

Settings and conduct
A three-blind clinical trial study in which an equal number of knee osteoarthritis patients referred to Waliasr Hospital in Arak were randomly divided into two groups and subjected to intervention with one of placebo treatments or cannabinoid cream. Before the start of the intervention, to know the initial condition of the patients, they are asked to answer the questions of the WOMAC questionnaire (individuals must stop taking other pain-relieving drugs for a week to ten days). Then, after starting the study and receiving the drugs, the patients fill the questionnaire again 12 weeks later. The study is triple-blind, and the researchers and analyzing patients do not know about the allocation of the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients over 18 years of age referred to the orthopedic clinic of Waliasr Hospital in Arak with complaints of pain caused by knee osteoarthritis and completed the written consent to participate in the study.

Intervention groups
Intervention: Cannabinoid receiving group Control: placebo recipient

Main outcome variables
Pain, Joint stiffness, Restriction of movement

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221218056851N2**
Registration date: **2023-12-03, 1402/09/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-03, 1402/09/12**
Update count: **0**

Registration date
2023-12-03, 1402/09/12

Registrant information

Name
Mona hamedi tabar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3417 3503

Email address
hamedimona.1996@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2024-01-30, 1402/11/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of local cannabinoid administration on knee osteoarthritis: A randomized triple-blind placebo based clinical trial

Public title

Effect of local cannabinoid administration on knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 years of age referred to the orthopedic clinic of Valiasr Arak Hospital with complaints of knee osteoarthritis pain.

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

To divide the patients into two groups A and B, the Restricted Randomization method was used according to the Random Allocation Rule. In this method, which is done using the random allocation software, 50 patients from They are numbered up to 50 and are divided into two groups A and B by the software. One group (group A) receives the placebo and group B receives the cream containing cannabinoids.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study is a three-blind study, a statistician who randomly places the patients in two groups receiving placebo and convert, without knowing the contents of the creams, he provides them to the patients. The researchers will be unaware of the grouping as well as the drugs that each group receives. Patients will also be unaware of the medicine they receive. In addition, the cream that is used as a placebo is completely similar to the cream containing cannabinoids in terms of appearance (color, smell, concentration, etc.) and packaging, and is indistinguishable for patients. Also, the researchers are not aware of how the drugs are distributed among the patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committees of Arak University of Medical Sciences

Street address

Arak Univercity of Medical Science, Arak

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2023-10-01, 1402/07/09

Ethics committee reference number

IR.ARAKMU.REC.1402.159

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Pain

Timepoint

immediately and 12 weeks after

Method of measurement

WOMAC (Western ontario and mcmaster universities index) questionnaire

2

Description

Joint stiffness

Timepoint

immediately and 12 weeks after

Method of measurement

WOMAC questionnaire

3

Description

Limitation of movement

Timepoint

immediately and 12 weeks after

Method of measurement

WOMAC questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Canvert cream is produced according to the order of Alasht Pharmed Company in Mon Rogin Company in Iran, Alborz Province and contains cannabidiol. How to use the cream, as mentioned in the cream brochure, put a sufficient amount of the product (a knuckle) on the skin of the desired area (knee) and massage it with your hand until it is completely absorbed. Patients use this cream twice a day for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: In the control group, a placebo is used. The placebo is also produced by Alasht Pharmed Company in Monrogin Company in Iran, Alborz Province, and has the same ingredients as Convert Cream, but does not contain cannabidiol. How to use the cream, as mentioned in the cream brochure, put a sufficient amount of the product (a knuckle) on the skin of the desired area (knee) and massage it with your hand until it is completely absorbed. Patients use this cream twice a day for 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Mohammad Reza Bozorgmanesh
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Sponsors / Funding sources

1

Sponsor
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Dr Mona Hamedi Tabar
Position
General physician
Latest degree
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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