

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 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 Waliar 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 Waliar 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 hamed 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 questionaire

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Convert 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

#### Street address

Valiasr hospital, Valiasr square, Arak

#### City

Arak

#### Province

Markazi

#### Postal code

3814957558

#### Phone

+98 86 3222 2003

#### Email

pr\_valieasr@arakmu.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Dr Davoud Hekmat Pou

#### Street address

Arak University of Medical Science, Arak

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#### Province

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#### Phone

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#### Email

research@arakmu.ac.ir

### 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 Hamed Tabar

#### Position

General physician

#### Latest degree

Medical doctor

#### Other areas of specialty/work

General Practitioner

#### Street address

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

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Dr Mona Hamedi Tabar

**Position**

General physician

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## Person responsible for updating data

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**Name of organization / entity**

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**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