

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Clinical trial of hybrid thermosensitive hydrogel based on hyaluronic acid containing celecoxib for knee osteoarthritis patients

#### Protocol summary

##### Study aim

The aim of this study is to develop a new group of temperature-sensitive hydrogels for intra-articular injection that show very stable and excellent drug release.

##### Design

A randomized clinical trial, with two intervention groups, phase 1, single-blind, sample size 84 people, blinding using sealed envelopes, randomization method using permuted block randomization

##### Settings and conduct

The samples will be selected from patients with mild to moderate arthritis in Shahid Kamyab Hospital and Seyedi Clinic in Mashhad. At this stage, first, the patient's medical history is taken to enter the demographic information of the person and to check the signs of entering and exiting the study, as well as the signs and symptoms related to the disease. If the person meets the criteria for entering the study and does not meet the criteria for exit, the final approval is based on the relevant expert's diagnosis.

##### Participants/Inclusion and exclusion criteria

Age 45 to 80 years, primary one-side knee osteoarthritis that has been symptomatic (painful) for at least six months.

##### Intervention groups

Patients with primary OA of the knee are randomly subjected to the injection of temperature-dependent hydrogel containing celecoxib or commercial Hyalgan gel.

##### Main outcome variables

The detailed range of motion and the sit-and-stand test (at three time points, months 2, 4 and 6) Evaluation of parameters related to the immune system IL-10, TNF-a, IL- 6, TGF-beta1 and ALT and AST and BUN and creatinine will be performed.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221101056363N1**

Registration date: **2022-11-22, 1401/09/01**

Registration timing: **prospective**

Last update: **2022-11-22, 1401/09/01**

Update count: **0**

##### Registration date

2022-11-22, 1401/09/01

##### Registrant information

##### Name

Mona Alibolandi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3180 1535

##### Email address

alibolandim@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-21, 1401/11/01

##### Expected recruitment end date

2023-09-23, 1402/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial of hybrid thermosensitive hydrogel based on hyaluronic acid containing celecoxib for knee osteoarthritis patients

#### Public title

The effect of injectable and sustained-release pharmaceutical form of celecoxib in the treatment of knee osteoarthritis patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Primary one-sided osteoarthritis of the knee that has been at least 6 months since it became symptomatic (painful) and aggravated by weight bearing and has not responded properly to conservative treatment.

Radiographic arthrosis stage 1, 2 and 3 of Kellgren Lawrence classification (KLS) Signing the consent form and complete and voluntary willingness to participate in the study

##### Exclusion criteria:

Any history of trauma (fracture), surgery and tumor in the knee and lower limb of the same side Clinically obvious alignment disorder Any history of invasive procedure, injection or infection in the desired knee during the last 6 months Any blood disorder History or history of autoimmune disease or being treated with immunosuppressors and non-removable corticosteroids Patients with secondary osteoarthritis Proven liver and kidney disorders Irrevocable consumption of oral or topical painkillers Cognitive impairments and the inability to walk without a walker or the help of others CVA and similar problems Insulin-dependent diabetic patients Patients with spine disorders and radicular pain to the lower limbs

#### Age

From **45 years** old to **80 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **84**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

In this study, the randomization method is the "permuted block randomization" method. with the following steps: 1- First, we fill the paper for the two treatments A and B with the number of sample size (84 patients) So that we assign 42 patients to A and another 42 patients to B. 2- We put the papers into the lottery bottle and mix thoroughly. We place each one randomly in an envelope. 3- Then patients will be randomly assigned to A and B groups through sealed envelopes.

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

#### Ethics committees

##### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

###### Street address

Vakyl Abad Boulevard, Mashhad University of Medical Sciences, School of Pharmacy

###### City

Mashhad

###### Province

Razavi Khorasan

###### Postal code

917751365

##### Approval date

2022-08-13, 1401/05/22

##### Ethics committee reference number

IR.MUMS.REC.1401.185

#### 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

Evaluation of the parameters related to the immune system including the level of IL-10, TNF-a, IL-6, TGF-beta1)

##### Timepoint

It will be performed at the beginning, second week and fourth weeks.

##### Method of measurement

Commercial lab kits

##### 2

##### Description

liver tests including the serum level of ALT and AST

##### Timepoint

It will be performed at the beginning, second week and fourth weeks.

## Method of measurement

Commercial kits

### 3

#### Description

BUN and creatinine

#### Timepoint

It will be performed at the beginning, second week and fourth weeks.

#### Method of measurement

Commercial kits

### 4

#### Description

Range of motion of the joint (goniometer and degree)

#### Timepoint

It will be performed at the beginning, second week and fourth weeks.

#### Method of measurement

goniometer and degree

### 5

#### Description

The sitting and standing test (number)

#### Timepoint

It will be performed at the beginning, second week and fourth weeks.

#### Method of measurement

Physical examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients with primary OA of the knee, who after checking the entry and exit criteria and signing the consent form, were randomly injected with temperature-dependent hydrogel containing celecoxib. The surgeon will repeat the injection at week 0, 2 and 4, 2 cc each time for each patient (6 cc in total).

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Patients with primary OA of the knee, who after checking the entry and exit criteria and signing the consent form, were randomly injected with Hyalgan gel. The surgeon will repeat the injection at week 0, 2 and 4, 2 cc each time for each patient (6 cc in total).

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kamyab and Seyed Hospitals

##### Full name of responsible person

Mona Alibolandi

##### Street address

Vakyl Abad Boulevard, Pardis complex, Pharmacy School

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##### Phone

+98 912 317 6810

##### Email

alibolandim@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mona Alibolandi

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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

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mona Alibolandi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Vakil Abad Boulevard, University Campus, Faculty of Pharmacy

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data including range of motion tests and blood tests will be shared.

**When the data will become available and for how long**

The access starts 2 months after the publication of the article and the patent. برای

**To whom data/document is available**

All academic and scientific researchers as well as industry are allowed access.

**Under which criteria data/document could be used**

All the analyzes will be done by us and will be provided to the researchers just to clarify the data.

**From where data/document is obtainable**

Refer to the person in charge of the project and Mashhad University of Medical Sciences.

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

An email will be sent to the university and the project manager.

**Comments**