Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 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 problemsInsulin-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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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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

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Person responsible for scientific inquiries

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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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Faculty

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Other areas of specialty/work
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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