

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Evaluation of the effect of "Arthroheal" Lipogel Herbal Medicine on Osteoarthritis Patients

#### Protocol summary

##### Study aim

Evaluation of the effect of "Arthroheal" Lipogel Herbal Medicine on Osteoarthritis Patients

##### Design

This study will be a double blind, prospective, randomized and comparative study. Seventy female and male patients will be selected from the rheumatology clinic of Mazandaran University of Medical Sciences and randomly divided into two groups, Lipogel The placebo group is divided into two groups, the second group taking lipogel containing the extract. To randomize the patients, we divided the patients into two groups according to the order of attendance at the numbering clinic and by random number table. Both groups are allowed to use Nsaid for ethics.

##### Settings and conduct

The study does under the supervision of a Rheumatologist at touba medical center . The randomized coded products are given to patients.

##### Participants/Inclusion and exclusion criteria

Men and women over 40 years of age with knee Osteoarthritis grade 1 and 2 based on x-ray, no previous history of OA, at least one month interval with latest intra-articular injection and no intra-articular injection during the study, no Lumbar Neurological disorder, no peripheral Neuropathy, no grade 3 and 4 Heart failure, no need for Diabetic dialysis

##### Intervention groups

The study included two intervention and control groups. The intervention group received lipogel containing extract twice a day and five times daily and the control group received placebo twice daily and five times daily.

##### Main outcome variables

Evaluation of pain relief in consumer patients

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20130911014630N9**

Registration date: **2020-05-04, 1399/02/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-05-04, 1399/02/15**

Update count: **0**

#### Registration date

2020-05-04, 1399/02/15

#### Registrant information

##### Name

Mohammad Azadbakht

##### Name of organization / entity

Mazandaran University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3354 3728

##### Email address

mazadbakht@mazums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-03-21, 1397/01/01

#### Expected recruitment end date

2020-05-21, 1399/03/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of the effect of "Arthroheal" Lipogel Herbal Medicine on Osteoarthritis Patients

## Public title

Evaluation of the effect of "Arthroheal" Lipogel Herbal Medicine on Osteoarthritis Patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Men and Women Over the Age of Forty years with Osteoarthritis in the Knee Area with Grade 1 and 2 No Previous Surgery History for Osteoarthritis An interval at Least one Month with the Latest Intra-Articular Injection and no Intra-Articular Injection During the Study

### Exclusion criteria:

Age less than a quarter of a year Diagnosis of Rheumatoid Arthritis Neurological Disorder of the Waist Peripheral Neuropathy Patient with Grade 3 and Grade 4 Heart Failure Diabetic Patient Undergoing Dialysis Malignant Patient Intra-articular Injection at Intervals of less than One Month or During the Study

## Age

From **40 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **70**

More than 1 sample in each individual

Number of samples in each individual: **3**

Three Number per Person according to Tube Volume

## Randomization (investigator's opinion)

Randomized

## Randomization description

On the First Day, Patients are Randomly Assigned to two Groups based on the number of Attending the Numbered Clinic.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Local Combination Gel and Placebo with 4-digit and Different Letter Codes and with the same Appearance At the Center for Clinical Evaluation, under the Supervision of a Specialist in Rheumatology and Orthopedics, Patients are provided.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

##### Street address

Prophet Mohammad Medical Sciences Complex.Farahabad Street

##### City

Sari

##### Province

Mazandaran

##### Postal code

48188-69378

#### Approval date

2020-01-01, 1398/10/11

#### Ethics committee reference number

IR.MAZUMS.REC.1398.1285

## Health conditions studied

### 1

#### Description of health condition studied

Osteoarthritis

#### ICD-10 code

M17

#### ICD-10 code description

Osteoarthritis of Knee

## Primary outcomes

### 1

#### Description

Womac Questionnaire Score

#### Timepoint

First Day, Fourteen and Sixty

#### Method of measurement

Womac Questionnaire Score

## Secondary outcomes

### 1

#### Description

VAS (Visual Analogue Scale) Questionnaires

#### Timepoint

First day, Fourteen, Sixty

#### Method of measurement

VAS (Visual Analogue Scale) Questionnaires

## Intervention groups

### 1

#### Description

Intervention Group 1: Female or General Patient with

Knee Osteoarthritis 1 and 2 According to Radiography with Daily Administration of 5 g of Lipogel Containing Drug for Two Months.The Patient is Allowed to Take Nsaid.

**Category**

Rehabilitation

**2**

**Description**

Control group 1: Female or general patient with knee osteoarthritis 1 and 2 according to radiography with 5 g daily of placebo for two months.The patient is allowed to take Nsaid.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Baghban's Specialized and Superior Specialized Slinic

**Full name of responsible person**

Maryam Mobini

**Street address**

Farah Abad Square.Khazar Boulevard

**City**

Sari

**Province**

Mazandaran

**Postal code**

48188-69378

**Phone**

+98 11 3324 0002

**Email**

Azadbakhtm@hotmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mohammad Azadbakht

**Street address**

Farah abad street

**City**

Sari

**Province**

Mazandaran

**Postal code**

4847191971

**Phone**

+98 11 3354 2472

**Fax**

**Email**

Azadbakhtm@hotmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mahnaz Siri

**Position**

Pharmacy student of Sari School of Pharmacy

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Farah Abad Street

**City**

Sari

**Province**

Mazandaran

**Postal code**

**Phone**

+98 51 3213 2065

**Email**

Mahnazshiri713@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mohamad Azadbakht

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Farah Abad Street

**City**

Sari

**Province**

Mazandaran

**Postal code**

6937848188

**Phone**

+98 911 151 3032

**Email**

Azadbakhtm@hotmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mahnaz Shiri

**Position**

Pharmacy Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Farah Abad Street

**City**

Sari

**Province**

Mazandaran

**Postal code**

48188-69378

**Phone**

+98 51 3213 2065

**Email**

Mahnaz.shiri713@gmail.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**

Results from clinical trials

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

Start access after printing the article

**To whom data/document is available**

Access for scholars working in academic institutions

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

Use of results is allowed only by mentioning its source

**From where data/document is obtainable**

azadbakhtm@hotmail.com

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

Request from the researcher

**Comments**