

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

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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

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Farah Abad Square.Khazar Boulevard

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

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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

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

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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

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

Mazandaran University of Medical Sciences

Full name of responsible person

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Position

Pharmacy Student

Latest degree

A Level or less

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

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