

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of clinical effects of sodium mannuronate and salicylate ointments in the reduction of activity and symptoms of disease in patients with osteoarthritis

Protocol summary

Summary

In this double-blind randomized controlled clinical trial (double-blind means that the patients and researchers are unknown about what kind of treatment has been provided). We use sodium mannuronate ointment as an anti-inflammatory drug in treatment of patients with osteoarthritis and effectiveness of this drug in involved patients will be compared with salicylate as another anti-inflammatory drugs. Our samples are 50 patients with osteoarthritis in the age range of 35 to 75 years, according to the diagnostic criteria of American College of Rheumatology will be selected at the first visit by a specialist in rheumatology in Rheumatology Research Center, Shariati Hospital and for each patients, the questionnaire will be completed. In the selection of these patients, no history of autoimmune disorders, infectious diseases, cancers and malignancies, as well as non-current pregnancy or breast feeding is considered. Then patients with block randomized method will be divided into control and treatment groups. Treatment group will be treated topically 3 times per day for 30 days with non-steroidal ointment called mannuronate sodium which its effective material has been produced in department of immunology, Tehran University of Medical Sciences and then is packaged by Tropical Drug Industry Kish Co. Control group is treated topically 3 times per day for 30 days with salicylate ointment produced by Sobhan Darou Co. After the treatment period, patients are re-examined by a specialist in rheumatology and related questionnaire is completed. The results will be compared to each other and therapeutic effect of this medication in reduction of the symptoms of osteoarthritis will be examined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014113013739N3**

Registration date: **2015-02-15, 1393/11/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-15, 1393/11/26

Registrant information

Name

Abbas Mirshafiey

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 4913

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical effects of sodium mannuronate and salicylate ointments in the reduction of activity and symptoms of disease in patients with osteoarthritis

Public title

Effect of sodium mannuronate ointment in osteoarthritis treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with osteoarthritis in the age range of 35 to 75 years, according to the diagnostic criteria of American College of Rheumatology which at the first visit by a specialist in rheumatology and then by laboratory and radiological parameters are diagnosed. Exclusion criteria: history of fever and infectious diseases, pregnancy and breast feeding, other autoimmune diseases, cancers and malignancies, the involvement of patients in the other clinical trials during the past 4 weeks, other diseases simultaneously (hepatic, nephrotic, hematologic, gastrointestinal, endocrine, cardiovascular, respiratory, neurologic or cephalic)

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Poursina Street, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2014-11-22, 1393/09/01

Ethics committee reference number

93-01-27-24686-131381

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M15.0

ICD-10 code description

Polyarthrosis

Primary outcomes

1

Description

Osteoarthritis activity

Timepoint

Before intervention and one month after intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Pain

Timepoint

Before intervention and one month after intervention

Method of measurement

Questionnaire

2

Description

Stiffness

Timepoint

Before intervention and one month after intervention

Method of measurement

Questionnaire

3

Description

Physical performance

Timepoint

Before intervention and one month after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Control group will be treated topically 3 times per day for 30 days with Salicylate ointment produced by Sobhan Darou Co.

Category

Treatment - Drugs

2

Description

Treatment group will be treated topically 3 times per day for 30 days with non-steroidal ointment called Mannuronate sodium which its effective material has been produced in department of immunology, Tehran University of Medical Sciences and then is packaged by Tropical Drug Industry Kish Co.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology Research Center, Shariati Hospital, Tehran University of Medical Sciences

Full name of responsible person

Ahmad Reza Jamshidi

Street address

Rheumatology Research Center, Shariati Hospital, Tehran University of Medical Sciences, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences (Major supporter)

Full name of responsible person

Masoud Younesyan (Vice President for Research and Technology, Tehran University of Medical Sciences)

Street address

Sixth floor of the Tehran University of Medical Sciences, Ghods Street, Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences (Major supporter)

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Abbas Mirshafiey

Position

Head Dept. of Pathobiology (Professor-PhD)

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty