

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The comparison Trial of Dextrose Prolotherapy compared to Corticosteroid injection for the treatment of symptomatic first carpometacarpal joint osteoarthritis

Protocol summary

Summary

Purpose: The comparison of the effectiveness of Dextrose and Corticosteroid injections on pain score reduction and functional improvement of hand, among people suffering from symptomatic first carpometacarpal joint osteoarthritis. Design: In the Physical medicine and Rehabilitation clinic of Imam reza Hospital, 30 hands are Randomized to each treatment arm,. The injections are intraarticular. We evaluate patients prior to the injection, then 1 , 2 and 6 months after the last injection. We measure the amount of pain on VAS scale, the hand functional assessment on HAQ-I scale and the gripping power on Pinch gauge. Inclusion criteria: First CMC joint osteoarthritis with pain and gripping disorder. Exclusion criteria: History of joint injury or injection in the prior 6 months. Intervention: in experimental group:10%Dextrose solution (3 injections monthly) and in control group: Methylprednisolone acetate solution (1 injection). Primary outcome: Decrease pain score >20% (6 months follow up). Secondary outcome :Grip strength and Functional assessment of hand.(6 months follow up). Side effects are recorded if any .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011025088N1**
Registration date: **2011-01-15, 1389/10/25**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-01-15, 1389/10/25

Registrant information

Name

Azadeh Jahangiri

Name of organization / entity

Army 501 (Imam reza hospital)

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2010-03-01, 1388/12/10

Expected recruitment end date

2011-03-01, 1389/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison Trial of Dextrose Prolotherapy compared to Corticosteroid injection for the treatment of symptomatic first carpometacarpal joint osteoarthritis

Public title

The comparison of the effectiveness of two injectable medications for the treatment of hand osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion:1-Age>40 2-First carpometacarpal joint pain over 3/10 on VAS scale with symptoms present greater

than 3 months 3-Confirmation of CMC osteoarthritis with radiography 4-The Gripping disorder in functional assessment scores 5-Ability to make follow up visits over the 6-month protocol. Exclusion:1-Recent trauma to the hand or fractures seen on radiographs 2-History of joint inflammatory or infectious disorder 3-Allergies to injected solutions 4-CMC joint injections in the prior 6 months.

Age

From **40 years** old to **90 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

501 Army university (research group)

Street address

Etemadzade street, west fatemi

City

Tehran

Postal code

1411718541

Approval date

2010-06-30, 1389/04/09

Ethics committee reference number

1019

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M15, M16,

ICD-10 code description

Arthrosis

Primary outcomes

1

Description

Pain

Timepoint

Before injection and 1, 2 and 6 months after the last injection

Method of measurement

VAS scale

Secondary outcomes

1

Description

Hand function and pinch grip strength

Timepoint

Before injection and 1, 2 and 6 months after the last injection

Method of measurement

HAQ-I scale and Pinch gauge

Intervention groups

1

Description

Experimental group: 20% Dextrose solution + 2% lidocain, 3 Injections monthly

Category

Treatment - Drugs

2

Description

Control group: Methylprednisolon Acetate solution, 40mg + Lidocain 2%, 1 Injecton

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The phisical medicine clinic of army hospital

Full name of responsible person

Dr Azadeh Jahangiri

Street address

Etemadzade, west Fatemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research group of 501 army university

Full name of responsible person

Dr Dormanesh

Street address

501 Army university, Etemadzade, West Fatemi

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research group of 501 army university

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**

501 Hospital

Full name of responsible person

Dr Azadeh Jahangiri

Position

Residency of physical medicine

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Web page address**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*