

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of the Effect of Collagen and Corticosteroid Intra-articular Injection on Function and Pain in Patients with First Carpometacarpal Joint Osteoarthritis

Protocol summary

Study aim

The purpose of this study is to investigate the effect of intra-articular injection of collagen and corticosteroids on the function and pain of patients with carpometacarpal joint osteoarthritis.

Design

This clinical trial study has a control group, with parallel groups, three blinded, randomized, phase 3 of clinical trial on 50 patients.

Settings and conduct

Subjects, interventionist, outcome assessor, statistician and the researcher are all blind to treatment groups allocation; us2 groups of 25 (injection of Steroid, collagen).The study will take place in Modares hospital.

Participants/Inclusion and exclusion criteria

Patients aged 40 to 70 years with first carpometacarpal osteoarthritis who are grade 2 and 3 based on radiographic criteria and have had moderate to severe pain in the first carpometacarpal joint for at least 3 months, which is resistant to drug treatment.

Intervention groups

Group one: patients who are treated with intra-articular injection of corticosteroids. Group two: patients who are treated with intra-articular injection of collagen.

Main outcome variables

Pain at the base of the thumb; the patient's performance in daily activities; The strength of the thumb; The need for painkillers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240126060813N1**

Registration date: **2024-03-04, 1402/12/14**

Registration timing: **prospective**

Last update: **2024-03-04, 1402/12/14**

Update count: **0**

Registration date

2024-03-04, 1402/12/14

Registrant information

Name

Seyed Mansoor Rayegani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

rayegani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-20, 1403/02/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Collagen and Corticosteroid Intra-articular Injection on Function and Pain in Patients with First Carpometacarpal Joint Osteoarthritis

Public title

Comparison of the Effect of Collagen and Corticosteroid Intra-articular Injection on Function and Pain in Patients with First Carpometacarpal Joint Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with first carpometacarpal osteoarthritis based on radiographic criteria grade 2 and 3 and have moderate to severe pain (VAS $\geq$ 5) in the first carpometacarpal joint for at least 3 months, which is resistant to drug treatment.

Exclusion criteria:

The patient's willingness to withdraw from the study at any stage of the design The presence of any acute or chronic infection of the joint or around the joint Pregnancy Any intra-articular injection of the first carpometacarpal joint was performed during the last three months. History of oral and systemic corticosteroid use in the last two weeks Use of NSAIDs within 2 weeks prior to injection Existence of inflammatory joint diseases such as rheumatoid arthritis, spondyloarthropathies, connective tissue diseases, gout, Paget's, septic arthritis History of neurological syndromes caused by entrapment of the peripheral nerves of the hands, such as carpal tunnel syndrome History of surgery in the hand Recent history of severe trauma to the hand Having a severe underlying disease such as uncontrolled diabetes Autoimmune and platelet disorders, treatment with anticoagulant and antiplatelet drugs within 10 days before injection Daily use of opioid and non-opioid analgesics Taking topical painkillers Hemarthrosis Erythema or psoriatic lesions at the injection site

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this clinical trial study, 50 patients with a diagnosis of first Carpometacarpal Joint Osteoarthritis will be included in the study randomly For random allocation of individuals in the study groups (intervention or intervention group and comparison or comparison group), the method of random allocation with block method (Block Randomization) will be used In this method, blocks with size of six (including three people in the intervention group and three people in the comparison group) with a ratio of 1: 1 will be used. Random Allocation software will be used to generate random sequences. For concealment, the random

allocation concealment method is used in such a way that random sequences are created. In this method, they are identified with two type of cards which are including group a (intervention group) and b (comparison group) and these cards are placed inside the sealed envelopes in order. In order to maintain the created sequence, numbering will be done on the outer surface of the envelopes. Finally, the numbered envelopes will be placed in a folder. Then, according to the order of entry of the eligible participants, the envelopes will be opened and the assigned group of the participant will be determined.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The researcher, patients and the collaborator of the project who will perform the statistical analysis will not be aware of the study. grouping of patients will be noted and will be shared to one of the partners.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical sciences, Shahid Arabi Street, Yaman Street, Shahid Chamran Highway, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-07-01, 1402/04/10

Ethics committee reference number

1402.166.IR.SBMU.MSP.REC

Health conditions studied

1

Description of health condition studied

First Carpometacarpal Joint Osteoarthritis

ICD-10 code

M18.1

ICD-10 code description

Unilateral primary osteoarthritis of first carpometacarpal

joint

2

Description of health condition studied

First Carpometacarpal Joint Osteoarthritis

ICD-10 code

M18.0

ICD-10 code description

Bilateral primary osteoarthritis of first carpometacarpal joints

Primary outcomes

1

Description

Pain in base of thumb

Timepoint

At the beginning of the study (before the start of the intervention) and one month and three months after the intervention

Method of measurement

Visual analogue scale (VAS)

2

Description

patient 's function

Timepoint

At the beginning of the study (before the start of the intervention) and one month and three months after the intervention

Method of measurement

FIHOA questionnaire scores

3

Description

The strength of the thumb

Timepoint

At the beginning of the study (before the start of the intervention) and one month and three months after the intervention

Method of measurement

Dynamometer

4

Description

The need for painkillers

Timepoint

At the beginning of the study (before the start of the intervention) and one month and three months after the intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 25 patients with osteoarthritis of the first carpometacarpal joint who will be treated with intra-articular injection of collagen.

Category

Treatment - Drugs

2

Description

Control group: 25 patients with osteoarthritis of the first carpometacarpal joint who will be treated with intra-articular injection of Corticosteroids.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres hospital

Full name of responsible person

Seyed Mansoor Rayegani

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Shahid Modarres hospital, Kaj square, Saadat abad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti 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?

No

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Faghihi Kashani

Position

Resident of Physical medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Physical Medicine and Rehabilitation Research Center,
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Person responsible for scientific inquiries

Contact

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Position

professor

Latest degree

Specialist

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Person responsible for updating data

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to

make this available

Title and more details about the data/document

All the data of people participating in this study can be shared after deidentifying people.

When the data will become available and for how long

The access period starts one year after the results are published

To whom data/document is available

Data of this study will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

If the goal of the researchers is to conduct a systematic review and meta-analysis on the data, the non-identifiable data of the patients will be provided to the researchers

From where data/document is obtainable

By sending an email to dmfk.pmr@gmail.com

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

Sending an email of requesting information and explaining the purpose and how to use the data

Comments