

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the therapeutic efficacy between corticosteroid injection with and without ultrasound guidance among patients with carpometacarpal 1 joint osteoarthritis

Protocol summary

Study aim

Comparison of therapeutic efficacy of corticosteroid injections by blind and ultrasound guided in patients with first carpometacarpal osteoarthritis

Design

Clinical trial with control group, single blind, randomized, Sample size: 40

Settings and conduct

The place of study will be Imam Khomeini Hospital, Tehran. In this study, patients do not know which study group they are in, because all patients see the sonographic probe. Therefore this study will be single-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age at least 18 years; Presence of pain on first CMC joint during rest or activity that lasted for at least 3 months; a VAS score of at least 3 before entering the study; Pain on touching the dorsum surface of the first CMC; Radiographic evidence of OA (grade 2,3). Non-inclusion criteria: Lack of access to patients for post-intervention investigations due to non-referral; Patient's willing to use systemic steroid or intra-articular injection other than injectable material under study; Radiographic evidence of severe osteoarthritis (grade 4); Previous history of CMC joint surgery; The history of any type of CMC injection over the past six months.

Intervention groups

Intervention group 1: Patients with first carpometacarpal joint arthritis undergoing ultrasound-guided corticosteroid injection. Intervention group 2: patients with first carpometacarpal joint arthritis undergoing corticosteroid injection using anatomic landmarks.

Main outcome variables

Pain; thumb strength; hand function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191015045119N1**

Registration date: **2020-04-05, 1399/01/17**

Registration timing: **retrospective**

Last update: **2020-04-05, 1399/01/17**

Update count: **0**

Registration date

2020-04-05, 1399/01/17

Registrant information

Name

Maryam Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6619 2291

Email address

m_hosseini100@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-15, 1398/07/23

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic efficacy between corticosteroid injection with and without ultrasound guidance among patients with carpometacarpal 1 joint osteoarthritis

Public title

Ultrasonnd use effect in thumb injection

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age at least 18 years old History of pain of first CMC joint during rest or activity that has last for at least 3 months Have VAS score at least 3 before entering the study Pain during touch of the dorsal surface of the CMC OA radiographic evidence of reduced articular space or osteophyte formation (grade 2,3) No response to common osteoarthritis treatments including oral and topical skin treatments, physiotherapy, exercise therapy, contrast bath

Exclusion criteria:

No patient access for post-intervention investigation due to no personal referral Patient's willing to use systemic steroids or intra-articular injection other than injectable drugs under the study Radiographic evidence of severe osteoarthritis (grade 4) Previous history of first carpometacarpal surgery History of any intra-CMC1 joint injection in the past six months Use of physiotherapy modality during the last 3 months Presence of steroid / lidocain injection contraindication such as sensitivity to these drugs and infection at the site of injection presence of a risk factor for intra-articular injection such as anti-coagulation use Poor control of diabetes, coagulation diseases, fractures, rheumatologic diseases, tumors, infections, gout, pregnancy or decision to get pregnant Severe deformity of the joint Acute trauma (last 3 months)

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups by using the four block randomization method. This method uses two letters A and B in which the letter A represents the patient in the first group (blind) and the letter B in the second group (ultrasound). Then two letters A and B will be written on some papers in six different arrangements, BAAB, AABBB, ABAB, BBAA, ABBA, BABA. we will randomly pick one of the papers and place the patients in order, according to the larrangement of the A and B letters. We will continue untile we achieve the desired sample size.

Blinding (investigator's opinion)

Single blinded

Blinding description

Ultrasound probes will be used in both groups and the device is switched on. In group A, the probe is not connected to the device while it is connected in group B. The patient is placed behind the monitor and does not know whether the probe is connected or not.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee on Biological Research

Street address

Imam Khomeini Hospital, Dr.Gharib Street, at the end of Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2019-10-14, 1398/07/22

Ethics committee reference number

IR.TUMS.IKHC.REC.1398.210

Health conditions studied**1****Description of health condition studied**

Osteoarthritis of the first carpometacarpal joint

ICD-10 code

M18.9

ICD-10 code description

Osteoarthritis of first carpometacarpal joint, unspecified

Primary outcomes**1****Description**

Pain severity

Timepoint

At baseline and 2, 6, and 12 weeks after injection

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Hand functional ability

Timepoint

At baseline and 2, 6, and 12 weeks after injection

Method of measurement

FIHOA questionnaire

3

Description

upper limb disability

Timepoint

At baseline and 2, 6, and 12 weeks after injection

Method of measurement

Quick-DASH Questionnaire

4

Description

Pinch power which is the power of thumb to squeeze something

Timepoint

At baseline and 2, 6, and 12 weeks after injection

Method of measurement

Dynamometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 (Carpometacarpal joint injection under ultrasound guide): In this group, after diagnosis, patients will be treated with corticosteroid injection into the 1st CMC joint under US guidance. After sterilizing the skin, the injection will be done with a 3-5 CC syringe and 27-25 Gauge needle and 1-1.5 inches in length, from the dorsal surface of the 1st CMC joint with 60 ° angle of the needle and in-plane probe from distal to proximal, entering the articular space. After aspiration, injection of 40 mg methylprednisolone with 0.5CC 2% lidocaine will be done.

Category

Treatment - Drugs

2

Description

Intervention group 2 (Carpometacarpal joint injection with anatomic landmarks): In this group, after diagnosis, patients will be treated with corticosteroid injection into the 1st CMC joint using anatomic landmarks. After sterilizing the skin, the injection will be done with a 3-5 CC syringe and 27-25 Gauge needle and 1-1.5 inches in length, from the dorsal surface of the 1st CMC joint with 60 ° angle of the needle , entering the articular space. After aspiration, injection of 40 mg methylprednisolone

with 0.5CC 2% lidocaine will be done.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Komeini hospital

Full name of responsible person

Maryam Hosseini

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Imam Khomeini hospital, Dr. Gharib street, at the end of Khashavarz boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Ali Sahraian

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Maryam Hosseini

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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

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Province

Tehran

Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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