Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 carpomethacarpal 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 carpomethacarpal joint arthritis undergoing ultrasound-guided corticosteroid injection. Intervention group 2: patients with first carpomethacarpal 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
Ultasound 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, AABB, 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
Street address
Imam Khomeini hospital, Dr. Gharib street, at the end of Kheshavarz 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
Street address
Tehran University of Medical Sciences, Poorsina street, Ghods street
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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

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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