

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the effectiveness of metacarpophalangeal static splint on pain reduction and function improvement of the adult patients with trigger finger

Protocol summary

Study aim

Determine the effectiveness of metacarpophalangeal static splint on pain reduction and function improvement of the adult patients with trigger finger

Design

Randomized clinical trial with two parallel group, with control group

Settings and conduct

The patients with trigger finger referred to the rehabilitation center at Shariati hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: 20-60 y/o Participate in other studies and interventions One affected finger No contraindication for injection All participants should receive and fill the consent forms No contraindication for splinting SST>2
Exclusion criteria: Patients with CNS disorder, peripheral neuropathy and osteoarthritis Who has proper cooperation in the course of study

Intervention groups

Group A: Methylprednisolone injection in pulley A1 Group B: Injection and splinting of MCP joint

Main outcome variables

Pain, functional status, hand's strength, stage of disease

General information

Reason for update

Record the actual sample size, the start and end date of the actual sampling and the end date of the trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20180804040685N3**

Registration date: **2020-09-09, 1399/06/19**

Registration timing: **prospective**

Last update: **2021-08-01, 1400/05/10**

Update count: **1**

Registration date

2020-09-09, 1399/06/19

Registrant information

Name

Hamid Reza Fateh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2110

Email address

hr-fateh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-04-09, 1400/01/20

Actual recruitment start date

2020-09-20, 1399/06/30

Actual recruitment end date

2021-04-21, 1400/02/01

Trial completion date

2021-07-21, 1400/04/30

Scientific title

Evaluation of the effectiveness of metacarpophalangeal static splint on pain reduction and function improvement of the adult patients with trigger finger

Public title

Evaluation of the effectiveness of metacarpophalangeal static splint on the adult patients with trigger finger

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

20-80 y/o The individuals should not have received similar treatments before and during this study One affected finger No contraindication for injection All participants should receive and fill the consent form No contraindication for splinting SST>2

Exclusion criteria:

The patients with CNS disorder, peripheral neuropathy and osteoarthritis Who has proper cooperation in the course of study

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After initial evaluation, samples will be assigned into one of the 2 groups A or B group using sealed envelopes, the patients have to pick up one the sealed envelopes, so their group will be defined randomly

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethic committee, Tehran University of Medical Sciences

Street address

Jalal Ale-Ahmad Highway

City

Tehran

Province

Tehran

Postal code

1417863181

Approval date

2019-12-12, 1398/09/21

Ethics committee reference number

IR.TUMS.VCR.REC.1398.691

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

The adult patients with trigger finger

ICD-10 code

M65.3

ICD-10 code description

Trigger finger

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

Functional status

Timepoint

Beginning of the study (before intervention), one month and three months after intervention

Method of measurement

Boston assessment questionnaire

2**Description**

Pain

Timepoint

Beginning of the study (before intervention), one month and three months after intervention

Method of measurement

Numeric pain rating

3**Description**

The strength of the fingers

Timepoint

Beginning of the study (before intervention), one month and three months after intervention

Method of measurement

Dynamometer

4**Description**

Stage of disease

Timepoint

Beginning of the study (before intervention), one month and three months after intervention

Method of measurement

Stages of stenosing tenosynovitis

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Injection (40 mg Methyl prednisolone) in pulley A1 and splinting of MCP joint; All injections would be made via insulin needle (gauge 29, and length 2.1 inch)

Category

Treatment - Devices

2

Description

Control group: Injection (40 mg Methyl prednisolone) in pulley A1; All injections would be made via insulin needle (gauge 29, and length 2.1 inch).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Saeed Reza Mehrpoor

Street address

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Email

hr-fateh@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Imam Khomeini Ave., Hasan Abad Sq., Sina Hospital
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deanmed@tums.ac.ir

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

Hamid Reza Fateh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Hamid Reza Fateh

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
Tehran University of Medical Sciences
Full name of responsible person
Hamid Reza Fateh
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Patient privacy

Study Protocol

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

Statistical Analysis Plan

Yes - There is 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

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

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after patient are not going to be identified

When the data will become available and for how long

6 months after the end of the study

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For use in related studies

From where data/document is obtainable

Corresponding Author

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

By email

Comments