

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Comparison of efficacy of ultrasound-guided midline and ulnar in-plane approach and blind midline approach triamcinolone acetonide injection in pain and fuction improvement among patients with carpal tunnel syndrome; A randomized clinical trial.

Protocol summary

Study aim

Comparison of efficacy of ultrasound-guided midline and ulnar in-plane approach and blind midline approach triamcinolone acetonide injection in pain and fuction improvement among patients with carpal tunnel syndrome

Design

Hospital based, double blind randomized trial with control group, three parallel arms with 15 patients in each group

Settings and conduct

Double blind Randomized controlled trial In this trial a total of 45 patients among those presenting to Shohadaye tajrish and Modarres hospitals with more than three months of symptoms will be enrolled and randomly assigned into three groups of 40 mg triamcinolone injection by ulnar in-plane, midline in-plane and blind approach.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18-65 years with mild or moderate carpal tunnel syndrome; and had symptoms lasted for 3 months at least. The exclusion criteria: Pregnant women; severe carpal tunnel syndrome; underlying diseases like diabetes mellitus, thyroid dysfunction and rheumatoid arthritis; history of injection for carpal tunnel within last 6 months; presence of concurrent neuropathy or radiculopathy.

Intervention groups

In one group inject 40 mg triamcinolone ulnar in-plane, second group inject midline in-plane and in control group inject 40 mg triamcinolone blindly.

Main outcome variables

Visual analog scale for pain; Boston questionnaire; Nerve conduction of median; Grip strength; Cross section area of median nerve

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130523013442N25**

Registration date: **2018-09-16, 1397/06/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-16, 1397/06/25**

Update count: **0**

Registration date

2018-09-16, 1397/06/25

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

Country

Iran (Islamic Republic of)

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+98 21 2273 1112

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a_raeissadat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-01, 1397/06/10

Expected recruitment end date

2019-05-05, 1398/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of ultrasound-guided midline and ulnar in-plane approach and blind midline approach triamcinolone acetonide injection in pain and function improvement among patients with carpal tunnel syndrome; A randomized clinical trial.

Public title

Comparison of efficacy of ultrasound-guided midline and ulnar in-plane approach and blind midline approach triamcinolone acetonide injection in pain and function improvement among patients with carpal tunnel syndrome; A randomized clinical trial.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who suffer from mild or moderate carpal tunnel syndrome. Participants aged between 18 to 65 years
Patients who had symptoms for at least 3 months

Exclusion criteria:

Women who were pregnant
Participants who had severe carpal tunnel syndrome
Patients who had past history of disorders like diabetes mellitus, thyroid dysfunction and rheumatoid arthritis
Patients who had history of local injection of steroids within last 3 months
Patients who had concomitant underlying neuropathy or radiculopathy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **2**
Patients with bilateral carpal tunnel syndrome will gain from different injection approaches.

Randomization (investigator's opinion)

Randomized

Randomization description

In the current study simple individualized block randomization method with three sealed envelopes will be used

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant and outcome assessor will be blinded about the patients' group

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

No. 1983969411, Shahid Beheshti University of Medical Sciences, Sahahid Arabi Street, Yaman Street, Shahid Chamran Highway, Velenjak

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Province

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Postal code

1983969411

Approval date

2017-11-07, 1396/08/16

Ethics committee reference number

IR.SBMU.MSP.REC.1396.534

Health conditions studied

1

Description of health condition studied

carpal tunnel syndrome

ICD-10 code

G56.00

ICD-10 code description

Carpal tunnel syndrome, unspecified upper limb

Primary outcomes

1

Description

Pain

Timepoint

Before intervention and 10 weeks after injection

Method of measurement

Visual Analogue Scale

2

Description

Function

Timepoint

Before intervention and 10 weeks after injection

Method of measurement

Boston questionnaire

3

Description

Sensory and motor nerve conduction

Timepoint

Before intervention and 10 weeks after injection

Method of measurement

Nerve electrophysiologic study

4**Description**

Median nerve size in ultrasound

Timepoint

Before intervention and 10 weeks after injection

Method of measurement

Cross section area of median nerve in inlet of carpal tunnel by ultrasound

Secondary outcomes

empty

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

Intervention group: Local ulnar in-plane injection of triamcinolon 40 mg by ultrasound

Category

Treatment - Drugs

2**Description**

Intervention group: Local midline in-plane injection of triamcinolon 40 mg by ultrasound

Category

Treatment - Drugs

3**Description**

Control group: Local blind injection of triamcinolon 40 mg by sham ultrasound

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohada Tajrish Hospital

Full name of responsible person

Mohammad Ahmadi Dastgerdi

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2**Recruitment center****Name of recruitment center**

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Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Seyed Ahmad Raeissadat

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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

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 Ahmadi Dastgerdi
Position
Resident in Physical Medicine and Rehabilitation
Latest degree
Medical doctor
Other areas of specialty/work
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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available