Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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)

Phone

+98 21 2273 1112

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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 fuction 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 fuction 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 diffrent 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
Tehran
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
Street address
Shahrdari street, Tajrish square, Shohada Tajrish Hospital
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2

Recruitment center
Name of recruitment center
Shahid Modarres Hospital
Full name of responsible person
Mohammad Ahmadi Dastgerdi
Street address
No. 1998734383, 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
Vice chancellor for research, Seyed Ahmad Raeissadat
Street address
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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

Physical Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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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