

# 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

##### Email address

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

##### City

Tehran

##### 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

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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  
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Physical Medicine  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Latest degree**  
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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