

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the two approaches, ulnar and radial injection with ultrasound guided in Carpal Tunnel Syndrome

Protocol summary

Study aim

our aim in this study is to compare the effectiveness of two different methods of ultrasound-guided local corticosteroid injection in the treatment of patient with carpal tunnel syndrome

Design

in this study forty patients with carpal tunnel syndrome referred to Firuzgar physical medicine and rehabilitation clinic, Tehran, Iran will be included in the study after qualifying the inclusion and exclusion criteria and obtaining the informed consent .patients will be randomly divided to two groups of twenty. For randomization we will use randomized blocking method

Settings and conduct

ultrasound-guided local injection of forty mg of triamcinolone with the in-plane method; in the first group with radial approach and in the second group with ulnar approach will be done by a physical medicine and rehabilitation specialist. Routine treatments including wrist splint for 6 weeks will be performed for all patients

Participants/Inclusion and exclusion criteria

in this study forty patients with carpal tunnel syndrome referred to Firuzgar physical medicine and rehabilitation clinic, Tehran, Iran will be included in the study after qualifying the inclusion and exclusion criteria and obtaining the informed consent

Intervention groups

patients will be randomly divided to two groups of twenty. For randomization we will use randomized blocking method

Main outcome variables

Electrodiagnostical and sonographic criteria, Boston questionnaire scores and VAS will be assessed in the 0, 2th week, 6th week and 12th week.

General information

Reason for update

Acronym

CTS,EMG-NCS, VAS, BQ-SS, BQ-SS

IRCT registration information

IRCT registration number: **IRCT20180205038619N1**

Registration date: **2018-03-05, 1396/12/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-09, 1397/11/20**

Update count: **1**

Registration date

2018-03-05, 1396/12/14

Registrant information

Name

Katayoun Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 6574

Email address

katayounmoradi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the two approaches, ulnar and radial injection with ultrasound guided in Carpal Tunnel Syndrome

Public title

Compare two different methods of ultrasound-guided corticosteroid injection in the treatment of carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Symptoms and signs of carpal tunnel syndrome (including pain and sensory disturbances in the Median nerve range) refer to the Physical Therapy and Rehabilitation Clinic and their disease is confirmed by EMG-NCS and Electrodiagnostic criteria have mild to moderate carpal tunnel syndrome They are entering the study

Exclusion criteria:

Severe Carpal Tunnel Syndrome with thenar atrophy
Symptoms
Contraindication of corticosteroid injection (including corticosteroid allergy and localized infections symptoms)
Diseases that immitate CTS symptoms, such as polyneuropathy, cervical radiculopathy, thoracic outlet syndrome
Surgical treatment or topical injection in the last six months. The origin of neoplastic or traumatic pain and fracture of the wrists.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blind study in which patients and outcomes analyzer are blinded. In order to blind the patient, it is said that both materials are effective for treatment, but the type of substance is not mentioned for patients when its injected. In order to blind the analyzer, the persons responsible for injection and data collection are different from the outcome assessors.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Ethics committee, Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-10-29, 1396/08/07

Ethics committee reference number

IR.IUMS.FMD.REC

Health conditions studied

1

Description of health condition studied

Carpal tunnel syndrome

ICD-10 code

G56.0

ICD-10 code description

Carpal tunnel syndrome

Primary outcomes

1

Description

The severity of symptoms and functional limitations

Timepoint

Zero, two, six and twelve weeks after

Method of measurement

By using Boston questionnaire

2

Description

The severity of symptoms

Timepoint

Zero, two, six and twelve weeks after

Method of measurement

Visual Analog Scale(VAS)

3

Description

Electrodiagnostic criteria

Timepoint

Zero, two, six and twelve weeks after

Method of measurement

By using EMG-NCV device

4

Description

Sonographic criteria
Timepoint
Zero, two, six and twelve weeks after
Method of measurement
By using Sonographic device

Secondary outcomes

1
Description
Side effects
Timepoint
Two, six and twelve weeks after
Method of measurement
Questionnaire

Intervention groups

1
Description
Intervention group: corticosteroid inject under the ultrasound-guid radial side of the median nerve which will be done by an experienced physical medicine and rehabilitation specialist using in-plane approach.
Category
Treatment - Other

2
Description
Intervention group: Intervention group: corticosteroid inject under the ultrasound-guid ulnar side of the median nerve which will be done by an experienced physical medicine and rehabilitation specialist using in-plane approach.
Category
Treatment - Other

Recruitment centers

1
Recruitment center
Name of recruitment center
Firouzgar Hospital
Full name of responsible person
Dr.Katayoun Moradi
Street address
Department of Physical Medicine and Rehabilitation,
Firuzgar Hospital, Valiasr Square, Tehran
City
Tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8214 1600
Email
h_firoozgar@yahoo.com

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed Ali Javad Mousavi
Street address
5th floor, Headquarters, Iran University of Medical Sciences, Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8214 1201
Email
admins@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Dr. Arash Babaei
Position
Associate Professor of Physical Medicine and Rehabilitation
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
Street address
Department of Physical Medicine and Rehabilitation,
Firuzgar Hospital, Valiasr Square, Tehran
City
Tehran
Province
Tehran

Postal code
1593747811
Phone
+98 21 8214 1229
Email
babaei-ghazani.a@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Arash Babaei
Position
Associate Professor of Physical Medicine and Rehabilitation
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
Street address
Department of Physical Medicine and Rehabilitation,
Firuzgar Hospital, Valiasr Square, Tehran
City
Tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8214 1229
Email
babaei-ghazani.a@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Katayoun Moradi
Position
Resident
Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine
Street address
میدان ولیعصر، بیمارستان فیروزگر، بخش طب فیزیکی و توانبخشی.
City
Tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8214 1229
Email
katayounmoradi69@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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 the patient's data can be shared with privacy in regard to patients name

When the data will become available and for how long

Start accessing 6 months after publishing the results.

To whom data/document is available

For scholars working in academic centers.

Under which criteria data/document could be used

It can be analyzed and printed by other people by mentioning the source

From where data/document is obtainable

katayounmoradi69@gmail.com

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

Upon authentication, data is provided to the individual.

Comments