Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the efficacy of steroid injection via proximal and distal approach on the symptoms and function in patients with mild and moderate Carpat Tunnel Syndrome

Protocol summary

Study aim
Determination of the results of steroid injection by proximal and distal methods on the symptoms and function of patients with mild to moderate carpal tunnel syndrome

Design
Two arm parallel group randomised clinical trial , design for 34 hands in each group, enrolled between

Settings and conduct
Population under study will include patients suspected of Carpal Tunnel Syndrome (CTS) referred to Iran Rehabilitation Center, from physical medicine and rehabilitation, orthopedic, and rheumatology clinics during 2018 time period

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) Mild to moderate CTS based on Electrodiagnostic findings; 2) Older than 18 years old; Exclusion criteria: 1) severe CTS with persistent pain & numbness; 2) a previous history of CTS injection 6 months ago; 3) a previous history of using CTS night splint; 4)a previous history of Carpal Tunnel Release surgry; 5) corticosteroid contraindication; 6) corticosteroid allergy; 7) Malignancy; 8) inflammation; 9) Pregnancy; 10) the presence of neurologic disorders; 11) Patients who have a surgical indication;

Intervention groups
Patients will be divided into two groups. First group will be injected by 40mg methyl prednisolone (proximal to crease); and, second group will be injected by 40mg methyl prednisolone (distal to crease) (palmar). It should be mentioned that both groups will use wrist static splint as a confirmed and standard treatment for a period of 3 months, just at nights

Main outcome variables
1.Electrodignostic findings 2. Comparison of symptom severity 3. Comparison of functional status

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
CTS

IRCT registration information
IRCT registration number: **IRCT20180804040685N1**
Registration date: **2018-11-07, 1397/08/16**
Registration timing: **prospective**

Last update: **2021-02-25, 1399/12/07**
Update count: **1**

Registration date
2018-11-07, 1397/08/16

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
2018-09-23, 1397/07/01

Expected recruitment end date
2019-03-11, 1397/12/20

Actual recruitment start date
2019-01-22, 1397/11/02

Actual recruitment end date

2019-12-11, 1398/09/20

Trial completion date

2020-03-11, 1398/12/21

Scientific title

Comparison of the efficacy of steroid injection via proximal and distal approach on the symptoms and function in patients with mild and moderate Carpat Tunnel Syndrome

Public title

Distal jnjection in Carpal tunnel syndrome ; Effect of Proximal injection in treatment of Carpal tunnel syndrome ;

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Mild to moderate CTS based on Electrodiagnostic findings
Older than 18 years old

Exclusion criteria:

Severe CTS with persistent pain & numbness; Previous history of CTS injection 6 months ago; Previous history of using CTS night splint; Previous history of Carpal Tunnel Release surgery ; Corticosteroid contraindication; Corticosteroid allergy; Malignancy; Inflammation; Pregnancy; Presence of neurologic disorders; Patients who have a surgical indication;

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**
Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the quadruple number block ;

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

Ethics committee of Tehran University of Medical Sciences

Street address

Jalal-Al-Ahmad Street; North Karegar Street;Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2018-09-18, 1397/06/27

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.444

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

Electrodignostic findings

Timepoint

Assessment of changes in electrodiagnostic tests at the beginning of the study (before intervention) and 3 months after steroid injection

Method of measurement

EMG-NCV machine

Secondary outcomes

1

Description

Symptom severity

Timepoint

Beginning of the study (before intervention) and 3 months after steroid injection

Method of measurement

Visual Analogue Scale

2

Description

Functional status

Timepoint

Beginning of the study (before intervention) and 3 months after steroid injection

Method of measurement

Boston carpal tunnel questionnaire

Intervention groups

1

Description

Intervention group : Injection (40 mg Methyl prednisolone) distal to crease; All injections would be made via insulin needle (gauge 29, and length 2.1 inch). Distal method injection takes place on volar section under wrist crease (palmar) and needle entrance angle would be 5-10 degrees or parallel to the arm (In this case wrist would be placed at dorsiflexion state 40-50 degrees). One and three months after the injection, patients will be reevaluated in terms of severity of symptoms and three months after the injection, patients will be reevaluated in terms of severity of symptoms and functional status (VAS- Boston questionnaires) .

Category

Treatment - Drugs

2

Description

Control group:Injection (40 mg Methyl prednisolone) proximal to crease; . All injections would be made via insulin needle (gauge 29, and length 2.1 inch). proximal method injection takes place in volar section (upper part of wrist crease) and medial side of Palmaris longus tendon; while, needle entrance angle is 30-40 degrees. One and three months after the injection, patients will be reevaluated in terms of severity of symptoms and functional status (VAS- Boston questionnaires) .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Mina Meshkini

Street address

Jalal-Al-Ahmad St; North karegar St; Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 2110

Email

meshkini83@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

Street address

No.1, Northern gate of the university, Poursina St, Enghelab St

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 6405 3491

Fax

Email

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

Mina Meshkini

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Jalal-Al-Ahmad St, North Karegar St,Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 2110

Email

meshkini83@yahoo.com

Person responsible for scientific 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

Street address
Jalal-Al-Ahmad St, North Karegar St,Tehran

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8940 2110

Email
meshkini83@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mina Meshkini

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

Street address
Jalal-Al-Ahmad St, North Karegar St, Tehran

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8490 2110

Email
meshkini83@yahoo.com

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

Statistical Analysis Plan
No - There is not a plan to make this available

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

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