

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of wrist mobilization compared with local corticosteroide injection in treatment of moderate carpal tunnel syndrome

Protocol summary

Study aim

Evaluation of the effectiveness of wrist mobilization compared with local corticosteroide injection in treatment of moderate carpal tunnel syndrome

Design

Two arm parallel group randomized trial with blinded outcome assessment

Settings and conduct

This study was conducted on patients referred to Aja University of Medical sciences in Imam Reza Hospital in 1395-1396. One of the doctors did not have any knowledge about the treatment provided to patients, and just evaluate the outcome. The other physician and the physiotherapist were only responsible for treating patients without knowing the functional status and severity of the patient's symptoms and pain.

Participants/Inclusion and exclusion criteria

Idiopathic moderate carpal tunnel syndrome approved by electrodiagnostic criteria Age of 30 to 60 years and with any sex

Intervention groups

This study was single-blind and it was performed on 58 hands with moderate CTS. Patients were randomly divided into two treatment groups with 29 samples. Group one was treated with local corticosteroid injection (40 mg Methylprednisolone acetate + 0.5 cc Lidocaine 2%) in the carpal tunnel. Group two was treated with carpal bone and Median nerve mobilization at wrist for ten sessions, every other day. Both groups received wrist splint with oral medication (Gabapentin tablet 100 mg and Vitamin B6 tablet 40 mg per day) for two month.

Main outcome variables

Electrodiagnostic parameters of Median nerve (sensory and motor latency and amplitude), pain intensity (based on visual analogue scale), symptom severity and functional status (based on Boston carpal tunnel questionnaire) and patient satisfaction.

General information

Reason for update

Acronym

CTS

IRCT registration information

IRCT registration number: **IRCT20180511039611N1**

Registration date: **2018-08-04, 1397/05/13**

Registration timing: **retrospective**

Last update: **2018-08-04, 1397/05/13**

Update count: **0**

Registration date

2018-08-04, 1397/05/13

Registrant information

Name

Hamideh Dehghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4382 3476

Email address

drdehghani.ha@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

2016-09-22, 1395/07/01

Actual recruitment end date

2017-12-22, 1396/10/01

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of wrist mobilization compared with local corticosteroide injection in treatment of moderate carpal tunnel syndrome

Public title

Study of the effect of wrist mobilization on carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Carpal tunnel syndrome approved by electrodiagnostic criteria Age 30 to 60 years old and with any sex

Exclusion criteria:

Atrophy of tenar muscle, mild or severe CTS based on electrodiagnostic study patient who was treated with anti-inflammatory drugs or physiotherapy modalities previous local steroids injection in a recent year or previous surgery for CTS Inflammatory joint disease, diabetes mellitus, thyroid disease Polyneuropathy, cervical radiculopathy, myelopathy Pregnancy

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **52**

Actual sample size reached: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done through randomized number table for mobilization & local injection groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study was conducted by two physicians and one physiotherapist. One of the doctors did not have any knowledge about the treatment provided to patients, and just did the median nerve conduction studies, assessed the pain, severity of symptoms, and functional status. The other physician was only responsible for treating patients without knowing the functional status and severity of the patient's symptoms and pain. Of course, in group two, the physiotherapist who performed manual therapy; had no knowledge about the status of the condition and the severity of the patient's symptoms and pain.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Aja University of Medical Sciences

Street address

Aja University of Medical Sciences, Shahid Etemadzadeh, West Fatemi St., Tehran, Islamic Republic of Iran

City

Tehran

Province

Tehran

Postal code

1411713116

Approval date

2016-10-03, 1395/07/12

Ethics committee reference number

IR.AJAUMS.REC.1395.16

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

Electrodiagnostic parameters of Median nerve (sensory and motor latency and amplitude)

Timepoint

Before and two months after treatment

Method of measurement

By electrodiagnostic device (Medtronic Dk-2740 denmark)

Secondary outcomes

1

Description

Pain intensity

Timepoint

Before, one and two months after treatment

Method of measurement

By visual analogue scale

2

Description

symptom severity and functional status

Timepoint

Before, one and two months after treatment

Method of measurement

By Boston carpal tunnel questionnaire

3

Description

Patient satisfaction

Timepoint

6 months after treatment

Method of measurement

By telephone

Intervention groups

1

Description

Intervention group two was treated with carpal bone and Median nerve mobilization at wrist for ten sessions, every other day; also received wrist splint with oral medication (Gabapentin tablet 100 mg and Vitamin B6 tablet 40 mg per day) for two month. Intervention group:

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr Sirous Azizi

Street address

Imam Reza Hospital, Aja University of Medical Sciences, Shahid Etemadzadeh, West Fatemi St., Tehran, Islamic Republic of Iran

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drdehghani.ha@Ajaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr Kamran Azma

Street address

Imam Reza Hospital, Aja University of Medical Sciences, Shahid Etemadzadeh, West Fatemi St., Tehran, Islamic Republic of Iran

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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

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Hamideh Dehghani

Position

Resident

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**

Artesh University of Medical Sciences

Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

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