Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 21 4382 3476

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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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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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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