Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effectiveness of carpal tunnel injection of corticosteroids and night splints, with daily splints in patients with carpal tunnel syndrome according to changes in the degree of symptoms based on assessment forms and electrodiagnostic study

Protocol summary

Study aim

Comparison of the effectiveness of local injection of corticosteroids and night splint with local injection of corticosteroids and day splints in patients with carpal tunnel syndrome.

Design

Clinical trial without control group, with parallel groups, double-blind, randomized, on 60 patients, It does not apply to phase. Permutation block method was used for randomization.

Settings and conduct

People will be divided into two treatment groups based on block randomization. In both groups, 40 mg methylprednisolone prednisolone was injected in an area slightly proximal to the distal fold of the wrist between the palmaris longus and flexor carpi radialis tendons at the volar level of the wrist. Then, in one group, a night splint will be prescribed, and in the other group, a daily splint will be prescribed. Also, for all patients, necessary training in the field of treatment process and activity and how to use The splint will be explained and also when the subjects enter the study and after 6 weeks, the symptom severity will be determined based on the VAS and Boston questionnaires, and the subjects will be subjected to electrodiagnosis and the relevant information will be recorded

Participants/Inclusion and exclusion criteria

Inclusion criteria: 25-65 year olds with mild to moderate CTS. Exclusion : Diabetes melitus, pregnancy, hypothyroidism, rheumatoid arthritis, inflammatory arthritis, polyneuropathy, alcoholism, infections, cervical disc pathologies, history of trauma and surgery.

Intervention groups

Methylprednisolone injection in both study groups and then using wrist splint daily in one group and nightly in the other group for 6 weeks.

Main outcome variables

Changes in nerve conduction velocity ,median nerve latency , VAS and boston index and comparison between 2 groups after injection and use of night and day wrist splint.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221020056249N1**
Registration date: **2022-12-11, 1401/09/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-11, 1401/09/20**
Update count: **0**

Registration date

2022-12-11, 1401/09/20

Registrant information

Name

Forouzan Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 5410

Email address

akbari.forouzan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-04, 1401/09/13

Expected recruitment end date
2023-06-20, 1402/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of carpal tunnel injection of corticosteroids and night splints, with daily splints in patients with carpal tunnel syndrome according to changes in the degree of symptoms based on assessment forms and electrodiagnostic study

Public title
Comparison of day and night splints in patients with CTS(carpal tunnel syndrome)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
25-64 y/o Patients diagnosed with mild to moderate CTS in electrodiagnostic study.
Exclusion criteria:
Pregnancy Diabetes Melitus Hypothyroidism Inflammatory Arthropathy Rheumatoid Arthritis Polyneuropathy Alcoholism Infections Cervical disc pathologies History of past trauma or surgery
Age
From **25 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The random allocation method in this study will be permutation block method. A represents a person who receives corticosteroid injections and daily splints, and B represents a person who receives corticosteroid injections and nightly splints. This method is based on blocks of four so that the total number of possible permutations of four is equal to 6: BAAB ABBA , BBAA ،AABB ،BABA ،ABAB Then, by using the table of random numbers and assigning a code from 0 to 9 to each of the permutations, the desired random list of 60 which includes 15 blocks of 4 is generated (using a computer) and the order of assigning each of the methods to Each of the samples participating in the study It is determined. In order to hide ,the random sequence method is used by another person who is unaware of the research process , and the questionnaires are completed by a person who is unaware of the division of groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Outcome assessor: Completed questionnaires and EDX findings are given to a person who is not aware of the interventions performed, and he is asked to rate the amount of pain reduction and increase in function and changes in nerve conduction velocity and latency according to the questionnaire and EDX findings. Data analyst: Finally, after completing and collecting all the information, the questionnaires are given to a person to check the information, who does not know about any of the work steps and how the intervention is divided.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
The central building of Shiraz University of Medical Sciences,across the Felestin Ave., Zand Ave.,Shiraz.
City
Shiraz
Province
Fars
Postal code
71348-14336
Approval date
2022-10-08, 1401/07/16
Ethics committee reference number
IR.SUMS.MED.REC.1401.343

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

VAS (visual analog scale) index for pain evaluation

Timepoint

At first and after 6 weeks of splint

Method of measurement

VAS questionaire

2

Description

BCTSQ(Boston Carpal Tunnel Questionnaire) index for function evaluation

Timepoint

At first and after 6 weeks of splint

Method of measurement

Boston questionaire

3

Description

NCV(nerve conduction velocity) and median nerve Latency in EDX(electrodiagnostic study)

Timepoint

At first and after 6 weeks of splint

Method of measurement

Electrodiagnostic study

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Injection of 40 mg of methylprednisolone is done in an area slightly proximal to the distal fold of the wrist between the palmaris longus and flexor carpi radialis tendons at the volar level of the wrist. Then a daily splint will be prescribed and also at the beginning of the study and after 6 weeks, the severity of symptoms will be determined based on the VAS and Boston questionnaires, and the subjects will be subjected to electrodiagnosis and the relevant information will be recorded.

Category

Treatment - Other

2

Description

Intervention group2: Injection of 40 mg of methylprednisolone is done in an area slightly proximal to the distal fold of the wrist between the palmaris longus and flexor carpi radialis tendons at the volar level of the wrist. Then a nightly splint will be prescribed and also at the beginning of the study and after 6 weeks, the severity of symptoms will be determined based on the VAS and Boston questionnaires, and the subjects will be subjected to electrodiagnosis and the relevant information will be recorded.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid faghihi Hospital

Full name of responsible person

Forouzan Akbari

Street address

Next to medical university, Zand Ave., Shiraz.

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2

Recruitment center

Name of recruitment center

Motahari Hospital

Full name of responsible person

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3

Recruitment center

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4

Recruitment center
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Full name of responsible person
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5

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Main building of medical science,Zand St., Shiraz.
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vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Forouzan Akbari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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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
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
Title and more details about the data/document
All collected deidentified IPD
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available
Academic institutions
Under which criteria data/document could be used
Practitoiners working in the same fields and who have CTS patients.
From where data/document is obtainable
Shiraz medical science university
What processes are involved for a request to access data/document
By making a request to the university
Comments