Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Our clinical trial is to evaluate the effectiveness of long term using of splinting in comparrison with short term usage of splinting in severe CTS in pt who do not accept surgical treatment.

Protocol summary

Summary

Research purposes:our purpose is to study the long term use of splint in carpal tunnel syndrome patients that rejected surgery therapy. Planing:it is an interventional study. Methodology:sample size:140 persons.The patients are randomly placed in two groups.One group receives the splint for six weeks and the other for six months.Both groups receives standard medical treatment (including NSAID and vitamin B6) in the same way. All the patients are investigated at the beginning and the end of the sixth week and the end of sixth month to examine the consequences. Inclusion criteria: patient with severe CTS that did not accept surgical treatment. Exclusion criteria :patient with previous surgery on the study hand or wrist; any mass; tumor; or deformity in the hand or wrist; any history of severe trauma to the wrist (such as fracture); polyneuropathy; cervical radiculopathy; pregnancy; or lactating ; fibromyalgia; and arthritis. Interventions :prescribing splint in a group for six weeks and six months for the other. The variables of the main consequences: development in electrodiagnostic parameters and Boston questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091814704N1**
Registration date: **2015-05-17, 1394/02/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-05-17, 1394/02/27

Registrant information

Name

Shahrzad Sanaee

Name of organization / entity

Shiraz University of Medical Sciences(SUMS)

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research ,Shiraz University of Medical Science

Expected recruitment start date

2012-12-28, 1391/10/08

Expected recruitment end date

2013-04-24, 1392/02/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Our clinical trial is to evaluate the effectiveness of long term using of splinting in comparrison with short term usage of splinting in severe CTS in pt who do not accept surgical treatment.

Public title

Effectiveness of long time using of splinting in severe CTS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient with severe cts that did not accept surgical treatment Exclusion criteria:patient with previous surgery on the study hand or wrist; any mass; tumor; or deformity in the hand or wrist; any history of severe trauma to the wrist (such as fracture); polyneuropathy; cervical radiculopathy; pregnancy; or lactating; fibromyalgia; arthritis

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

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 shiraz universty of medical science

Street address

3rd floor, managment building of shiraz university of medical sciences, Zand Avenue.

City

Shiraz

Postal code

Approval date

2014-08-03, 1393/05/12

Ethics committee reference number

CT-2014-224

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

EMG and NCV are the primary outcomes measurements that at the end they determinate the efficacy of the splint for the study

Timepoint

at the begining and at the end

Method of measurement

CTSAQ,Boston questionaire

Secondary outcomes

1

Description

clinical manifestations

Timepoint

every 2 weeks

Method of measurement

physical exam

Intervention groups

1

Description

The intervention group will receive (naproxene 500mg 3times a day) for 10 days and vit B1 B6 tabs for 6month.They use splint for 6 months

Category

Rehabilitation

2

Description

The control group:The patients use splint for 6 weeks.They will receive (naproxene 3 times a day) for 10 days and Vit B1 B6 for 6 months .

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical medicine and Rehabilitation clinics of Fghihi hospital

Full name of responsible person

Dr.Sharareh Roshanzamir

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Faghihi hospita ,Zand Avenue ,Shiraz

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Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research ,Shiraz University of Medical Science
Full name of responsible person
Dr.Postfrosh
Street address
Platform 7 , management building of Shiraz University of medical science ,Zand Avenue ,shiraz
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research ,Shiraz University of Medical Science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary

empty