

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

Iran (Islamic Republic of)

#### Phone

+98 71 3235 1087

#### Email address

sanaeesh@sums.ac.ir

#### 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 questionnaire

**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

**Street address**

Faghihi hospita ,Zand Avenue ,Shiraz

**City**

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.Postfrosch

**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*

## Person responsible for general inquiries

**Contact****Name of organization / entity**

International branch of Shiraz University of Medical Science

**Full name of responsible person**

Shahrzad Sanaee

**Position**

Intern

**Other areas of specialty/work****Street address**

Door plate:71, Street number 1, Jahad Sazandegi Avenue, Azadi plaza, Shiraz

**City**

Shiraz

**Postal code**

7144716699

**Phone**

+98 71 3227 4250

**Fax****Email**

shahrzad.sanaee@gmail.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shiraz University of Medical Science

**Full name of responsible person**

Dr.Sharareh Roshanzamir

**Position**

Assistant professor of Rehabilitation and physical medicine

**Other areas of specialty/work****Street address**

Physical medicine and Rehabilitation ward's off, second floor, Faghihi Hospital, Zand Avenue, Shiraz

**City**

Shiraz

**Postal code****Phone**

+98 71 3235 1087

**Fax****Email**

sharareh.roshanzamir@gmail.com

**Web page address**

## Person responsible for updating data

**Contact****Name of organization / entity****Full name of responsible person**

Shahrzad Sanaee

**Position**

Intern

**Other areas of specialty/work****Street address**

Door plate 89,street number 88,Ghasrodasht Avenue,Shiraz

**City**

Shiraz

**Postal code****Phone**

00

**Fax****Email**

shahrzad.sanaee@gmail.com

**Web page address**

## 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*