Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of wrist limited dynamic splint on the upper extremity function of women with carpal tunnel syndrome

Protocol summary

Summary

In this study we have designed a wrist limited dynamic splint for women with mild or moderate carpal tunnel syndrome which allow the wrist to extends up to 15 degrees and flexes up to 15 degrees. The trait of this splint allows the patient to have treatment and do their activities of daily living at the same time. The subjects of both treatment and control group will be received the routine treatment of rehabilitation but just the treatment group will receive the splints. The results of this study would be scores of Boston carpal tunnel syndrome questionnaire, grip and pinch strength, dexterity purdue peg board test, sensory conductive velocity and sensory distal latency of median nerve. These tests will be performed before and after the 6 weeks treatment.

General information

Acronym

WLDS for CTS

IRCT registration information

IRCT registration number: **IRCT2015061522753N1**

Registration date: **2015-11-27, 1394/09/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-27, 1394/09/06

Registrant information

Name

Seyede Marjan Jaladat

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 917 634 6493

Email address

m-jaladat@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-06-19, 1394/03/29

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of wrist limited dynamic splint on the upper extremity function of women with carpal tunnel syndrome

Public title

Effects of wrist limited dynamic splint on carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the subjects gender should be female; the patients diagnosis should be carpal tunnel syndrome by a physiatrist doctor; the severity of illness should be mild or moderate; the subjects should be able to understand and do the orders of the tests. Exclusion criteria: history of surgery on the affected hand; systemic illnesses; pregnancy; subjects who do not cooperate; subjects who do not have the results of neural conductive tests.

Age

From **20 years** old to **60 years** old

Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **24**
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
Tehran Unversity of Medical Sciences
Street address
Tehran Unversity of Medical Sciences, Qhods St., Keshavars boulvard
City
Tehran
Postal code
1417614411
Approval date
2015-11-25, 1394/09/04
Ethics committee reference number
IR.TUMS.REC.1394.1272

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
Function
Timepoint
Before and after the 6 weeks treatment
Method of measurement
Boston carpal tunnel syndrome questionnaire

2

Description
Symptome severity
Timepoint
Before and after the 6 weeks treatment
Method of measurement
Boston carpal tunnel syndrome questionnaire

3

Description
Grip strength
Timepoint
Before and after the 6 weeks treatment
Method of measurement
MIE digital device

4

Description
Pinch strength
Timepoint
Before and after the 6 weeks treatment
Method of measurement
MIE digital device

5

Description
Dexterity
Timepoint
Before and after the 6 weeks treatment
Method of measurement
Purduepeg board test

6

Description
Median nerve sensory conductive velocity
Timepoint
Before and after the 6 weeks treatment
Method of measurement
MEDLEC SYNERGY VIASIS electromiography device

7

Description
Median nerve distal sensory latency
Timepoint
Before and after the 6 weeks treatment
Method of measurement
MEDLEC SYNERGY VIASIS electromiography device

Secondary outcomes

empty

Intervention groups

1

Description
The treatment group would receive routine rehabilitation treatment beside the wrist limited dynamic splint
Category
Rehabilitation

2

Description
the control group would receive routine rehabilitation treatment without splint
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi hospital
Full name of responsible person
Seyede Marjan Jaladat
Street address
Zand street
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mehdi Abdolvahab
Street address
Occupational therapy department, Rehabilitation school, Pich Shemiran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
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
Tehran University of Medical Sciences
Full name of responsible person
Seyede Marjan Jaladat
Position
MSc student
Other areas of specialty/work
Street address
Sixth st., Golestan boulvard, Tahmasebi street
City
Shiraz
Postal code
7145746598
Phone
+98 71 3225 5978
Fax
Email
jaladatot@gmail.com; m-jaladat@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Seyede Marjan Jaladat
Position
BS of occopational therapy
Other areas of specialty/work
Street address
Sixth st., Golestan boulvard. Tahmasebi street.
City
Shiraz
Postal code
7145746598
Phone
+98 712255978
Fax
Email
jaladatot@gmail.com; m-jaladat@razi.tums.ac.ir; marjanjaladatot87@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Seyede Marjan Jaladat
Position
MSc student
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Street address

Sixth st., Golestan boulvard, Tahmasebi street

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Email

jaladatot@gmail.com; m-jaladat@razi.tums.ac.ir; marjanjaladatot87@yahoo.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