Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparative assessment of splinting and splinting plus local steroid injection outcomes in severe carpal tunnel syndrome

Protocol summary

Summary

patients with severe carpal tunnel syndrome, referred to outpatient clinics of physical medicine and rehabilitation affiliated to Isfahan University of Medical Sciences (2012-2013). Inclusion criteria consist of patients with signs and symptoms of CTS aged ≥18 years؛ and electrodiagnostic evidences of severe CTS. Exclusion criteria consist of Patients with secondary causes of CTS؛ conditions affecting treatment outcomes؛ as well as patients with thenar muscles atrophy due to advanced CTS. patients are selected by the simple random sampling method and are randomly allocated in two intervention groups (A and B).The sample size is estimated total number of 56 patients and 28 patients in each group. One group of patients (group A) is prescribed to use full time neutral wrist splint for a 12 weeks period. Group B is injected with 40 mg Depomedrol and prescribed to use the full time neutral wrist splint during the study period for 12 weeks. F/U criteria consist of electrodiagnostic parameters, Boston Questionnaire (BQ), and patients' satisfaction. Baseline characteristics of the studying population are recorded using electrodiagnostic parameters, Boston Questionnaire and patients' satisfaction. Studying population are reevaluated using Boston Questionnaire and patients' satisfaction after 4 weeks and all of F/U criteria 12 weeks after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050622130N1**
Registration date: **2015-07-19, 1394/04/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-07-19, 1394/04/28

Registrant information

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Sayed Amir Ebrahim Mahmoodian
Name of organization / entity
Isfahan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative assessment of splinting and splinting plus local steroid injection outcomes in severe carpal tunnel syndrome

Public title

Effectiveness of splinting and local steroid injection in severe carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with signs and symptoms of CTS aged ≥18 years؛electrodiagnostic evidences of moderate to severe CTS. Exclusion criteria: Patients with secondary causes of CTS (diabetes mellitus؛ thyroid dysfunction؛ malignancy؛ distal radius fracture؛ pregnancy)؛ conditions affecting treatment outcomes (cervical disc herniation؛ fibromyalgia؛ coexisting neuropathy؛ previous steroid injection into the affected wrist)؛ patients with thenar muscles atrophy due to advanced CTS.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **56**

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
Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jarib Av.

City
Isfahan

Postal code
8174673461

Approval date
2013-05-01, 1392/02/11

Ethics committee reference number
392162

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
clinical and functional status

Timepoint
baseline, 4 weeks and 12 weeks later

Method of measurement
Boston Questionnaire

2

Description
electrodiagnostic findings

Timepoint
baseline and 12 weeks later

Method of measurement
electromyography instrument

3

Description
patients satisfaction

Timepoint
baseline, 4 weeks and 12 weeks later

Method of measurement
Likert scale

Secondary outcomes

1

Description
local steroid injection complications

Timepoint
after injection,4 weeks and 12 weeks later

Method of measurement
patients complaints and physical examination

Intervention groups

1

Description
One group (group A) is prescribed to use full time neutral wrist splint for 12 weeks.

Category
Treatment - Other

2

Description
In group B using sterilized method and a 25G needle, 40mg methylprednisolone acetate (Depomedrol) is injected to the wrist-flexon crease just ulnar to the palmaris longus tendon. The needle is introduced with a 30 ° angle. If the patient complains of pain and

paresthesia in hand, the needle is withdrawn and re-positioned. Then patients are prescribed to use the full time neutral wrist splint during the study period for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra educational hospital

Full name of responsible person

Sayed Amir Ebrahim Mahmoodian

Street address

Alzahra hospital, Sofeh Av., Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Mehdi Nematbakhsh

Street address

Isfahan University of Medical Sciences, Hezar Jarib Av.

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan 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

Isfahan University of Medical Sciences, Medical faculty

Full name of responsible person

Dr. Sayed Amir Ebrahim Mahmoodian

Position

MD, Resident of Physical Medicine and Rehabilitation

Other areas of specialty/work

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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