

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effectiveness of extracorporeal shock wave therapy and wrist splint versus wrist splint for management of carpal tunnel syndrome

Protocol summary

Summary

The effectiveness of extracorporeal shock wave therapy and wrist splint versus wrist splint for management of carpal tunnel syndrome .A single blind randomized controlled trial. subjects:Patients 18-70 years of age; tingling and numbness or hand pain more than 1 month; mild to moderate carpal tunnel syndrome by electrophysiological study. Exclusion criteria:severe carpal tunnel syndrome; pregnancy; previous carpal tunnel decompression surgery in affected hand; corticosteroid injection to the carpal tunnel within last 3 months; history of wrist fracture in affected hand.Sample size:40.Intervention: Extracorporeal shock wave therapy and wrist splint versus wrist splint for management of carpal tunnel syndrome.patients of both groups receive wrist splint and ergonomic training for 12 weeks. patients of intervention group also receive 3 sessions of ESWT once a week.Outcome:change in tingling and pain and EDX parameters assessed with visual analog scale, persian version quick DASH questionnaire and nerve Conduction Study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014083118991N1**

Registration date: **2014-10-16, 1393/07/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-16, 1393/07/24

Registrant information

Name

Fatemeh Ghazaei

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Science

Expected recruitment start date

2014-10-08, 1393/07/16

Expected recruitment end date

2014-12-07, 1393/09/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of extracorporeal shock wave therapy and wrist splint versus wrist splint for management of carpal tunnel syndrome

Public title

The effectiveness of extracorporeal shock wave therapy and wrist splint for management of carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients 18-70 years of age; tingling and numbness or hand pain more than 1 month; vas equal or more than 4; positive tinel's sign or phalen's test; confirmed mild to moderate carpal tunnel syndrome by electrophysiological study. Exclusion criteria: severe

carpal tunnel syndrome; pregnancy; previous carpal tunnel decompression surgery in affected hand; corticosteroid injection to the carpal tunnel within last 3 months; history of wrist fracture in affected hand; abnormal EDX findings except carpal tunnel syndrome such as radiculopathy or polyneuropathy.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Science

Street address

Tehran, Shahid Hemat Highway, Iran University of Medical Science

City

Tehran

Postal code

Approval date

2014-10-01, 1393/07/09

Ethics committee reference number

933170/105

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

tingling and pain intensity

Timepoint

before beginning treatment, 3, 8 and 12 weeks after treatment

Method of measurement

visual analog scale

2

Description

severity of symptoms and functional status

Timepoint

before beginning treatment, 3, 8 and 12 weeks after treatment

Method of measurement

persian quick DASH questionnaire

3

Description

sensory and motor distal latency and amplitude of median nerve

Timepoint

Before beginning treatment, 3, 8 and 12 weeks after treatment

Method of measurement

EDX evaluating (nerve Conduction Study)

Secondary outcomes

1

Description

Any side effect after intervention

Timepoint

during ESWT therapy, 3, 8 and 12 weeks after therapy

Method of measurement

Ask from patient

Intervention groups

1

Description

intervention : ESWT receive in 3 sessions once a week. each patient receive ESWT over median nerve at carpal tunnel while the patient's forearm is placed on the table with the palm facing up with this protocol: 1000 shocks at a frequency of 6 Hz and energy level of 1.5 bar while probe is oriented perpendicular to patient's palm and ultrasound gel is used as a coupling agent. All patients receive wrist night splint in a neutral position with ergonomic training including avoidance of repeated and extreme wrist movements for 12 weeks.

Category

Treatment - Devices

2

Description

control:patients of control group receive wrist night splint in a neutral position with ergonomic training including avoidance of repeated and extreme wrist movements for 12 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Fatemeh Ghazaei

Street address

Tehran, Valiasr Square, Behafarin Street, Firoozgar Hospital

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University Of Medical Science

Full name of responsible person

Dr Bijan Forough

Street address

Tehran, Valiasr square, Behafarin Street, Firoozgar Hospital

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University Of Medical Science

Full name of responsible person

Fatemeh Ghazaei

Position

Physical Medicine and Rehabilitation resident/MD

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