

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparing the effect of physiotherapy and physiotherapy accompanied by acupuncture on pain, functional ability, grip strength and treatment efficacy in patients with carpal tunnel syndrome

Protocol summary

Study aim

comparing the effect of physiotherapy and physiotherapy accompanied by acupuncture on pain; functional ability; grip strength and treatment efficacy in patients with carpal tunnel syndrome

Design

superiority, parallel group Stratified randomization clinical trial with blinded outcome assessment.

Settings and conduct

The study population included patients with carpal tunnel syndrome whose disease was confirmed by an orthopedic specialist and referred to the clinics of Mashhad University of Medical Sciences. Patients will receive informed consent form approved by the Ethics Committee of Mashhad University of Medical Sciences if they are eligible for inclusion and if they wish to participate in the study. The therapist and assessor are two different individuals and neither intervention group will be aware. Physiotherapy was similar in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with clinical symptoms of carpal tunnel syndrome for more than one month.
Exclusion criteria: Pregnant women, have history of surgery and fracture, having systemic diseases, having grade 3 carpal tunnel syndrome, having contraindications of acupuncture.

Intervention groups

receive physiotherapy in one group and physiotherapy accompanied acupuncture in other group

Main outcome variables

pain; functional ability; grip strength; treatment efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190401043148N1**

Registration date: **2020-01-16, 1398/10/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-16, 1398/10/26**

Update count: **0**

Registration date

2020-01-16, 1398/10/26

Registrant information

Name

Mahsa Zaferanieh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of physiotherapy and physiotherapy accompanied by acupuncture on pain, functional ability, grip strength and treatment efficacy in

patients with carpal tunnel syndrome

Public title

Comparing the effect of physiotherapy and physiotherapy accompanied by acupuncture in patients with carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having symptoms for more than a month Having clinical symptoms to diagnose carpal tunnel syndrome

Exclusion criteria:

Being pregnant History of hand surgery have carpal tunnel syndrome grade 3 receive treatment or injection in past 6 month History of systemic disease Having a wrist fracture acupuncture Prohibition

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The envelope method is that the envelopes will be prepared and Random Numbers printed by a member of the Research Team with the help of the Randomaize.com site and placed inside the envelope. sealed envelope content not visible from the outside. We provide 2 envelopes, including physiotherapy and physiotherapy with acupuncture, and place the envelopes in two boxes separated by gender so that we have 20 sealed envelopes in each box containing 10 physiotherapy and 10 Physiotherapy with acupuncture, like the other box , first the purpose of the study is explained to the person who meets the conditions, and will be included in the study if they complete a written informed consent form. they are according to gender take envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome assessor will not be aware of the intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Building Ghoreshi, Central Organization of Mashhad University of Medical Sciences, Daneshgah Avenue, Mashhad, Iran.

City

Mashhad

Province

Razavi Khorasan

Postal code

1394491388

Approval date

2019-03-10, 1397/12/19

Ethics committee reference number

IR.MUMS.REC.1397.311

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

pain

Timepoint

pre test; post test

Method of measurement

visual analog scale

2

Description

functional ability

Timepoint

before intervention, after intervention

Method of measurement

BCT Questioner, Quick DASH

3

Description

grip strength

Timepoint

before intervention, after intervention

Method of measurement

dynamometer

Secondary outcomes

empty

Intervention groups

1

Description

control group: individuals will receive 10 sessions of physiotherapy 3 sessions per week and each session will last about 45 to 60 minutes. In addition to routine procedures (electrotherapy including tennis and ultrasound and watt pack), patients were also treated with a program of stretching exercises with hand techniques (nerve and tendon gliding exercises techniques)

Category

Treatment - Other

2

Description

Intervention group: In the physiotherapy group with acupuncture, the physiotherapy program is standard conservative methods, and similar with control group. And also in 3 physiotherapy sessions, patients receive acupuncture for 2 minutes in addition. Acupuncture is performed by the acupuncture specialist in Tai Yin, Hegu, ASHI, Neiguan points after disinfection of the site and using disposable needles of equal depth and angle.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr Hossein Negahban

Street address

Emam Reza Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Hossein Negahban

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Hossein Negahban

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available