# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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 accompained acupuncture in other group

**Main outcome variables**
pain; fanctional 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**

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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**
fanctional 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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9137913316
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Dr Mohsen Tafaghodi
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tafaghodim@mums.ac.ir
**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
**Street address**
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## Person responsible for scientific inquiries

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**Other areas of specialty/work**
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## Person responsible for updating data

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**Latest degree**
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**Other areas of specialty/work**
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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