

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparison of the effect of 4 weeks of cupping and kinesiotype on reducing the symptoms of carpal tunnel syndrome during pregnancy (ultrasonography)

Protocol summary

Study aim

Comparison of the effect of 4 weeks of cupping and kinesiotype on changing the symptoms of carpal tunnel syndrome during pregnancy (ultrasonography)

Design

Pregnant women will be divided into two groups: kinesiotype and cupping after being diagnosed with CTS. In the cupping group, air cupping will be used in the anterior region of the hand. These treatments will last for 8 sessions and two days a week and in total for 4 weeks. In the kinesiotype group, the I-shaped kinesiotype strip will be measured from the proximal palmar fold to the internal epicondyle of the humerus, then a Y-section will be made on the kinesiotype strip.

Settings and conduct

In this clinical trial, 30 pregnant women (30 hands) with carpal tunnel syndrome will be selected from among the patients referred to the gynecology clinic of the 3rd Shaban Hospital with the diagnosis of a gynecologist with an age range of 20 to 35 years.

Participants/Inclusion and exclusion criteria

Entry requirements: 1- The examinees are in the third trimester of pregnancy 2- The examinees are in the age range of 20 to 35 years 3- Dominant hand with carpal tunnel syndrome No entry conditions: 1- History of injury due to trauma to the median nerve or wrist such as bruises, fractures 2- Tested people should have CTS before pregnancy 3- Multiple births 4- Skin sensitivity to kinesiotype in some subjects

Intervention groups

In the cupping group, air cupping was used in the anterior region of the hand. In the kinesiotype group, an I-shaped band was measured from the proximal palmar fold to the internal epicondyle of the humerus. A Y-slice was then made on the kinesiotype strip.

Main outcome variables

Pain intensity, Boston questionnaire symptom severity,

Boston questionnaire functional status, median nerve cross section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151128025265N3**

Registration date: **2021-05-12, 1400/02/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-12, 1400/02/22**

Update count: **0**

Registration date

2021-05-12, 1400/02/22

Registrant information

Name

Sedigheh Sadat Naimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7756 1411

Email address

naimi.se@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-02, 1400/01/13

Expected recruitment end date

2022-09-20, 1401/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of 4 weeks of cuping and kinesiotype on reducing the symptoms of carpal tunnel syndrome during pregnancy (ultrasonography)

Public title
Comparison of the effect of 4 weeks of cuping and kinesiotype in patients with carpal tunnel syndrome during pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The subjects are in the third trimester of pregnancy The subjects are in the age range of 20 to 35 years Dominant hand with carpal tunnel syndrome Ultrasonographic findings should be positive in all subjects (increase in median cross-sectional area of more than 9 mm2)
Exclusion criteria:
History of trauma to the median nerve or wrist such as bruises, fractures Pre-pregnancy test takers have CTS Multiple births Skin sensitivity to kinesiotype in some subjects Diabetes Rheumatoid Arthritis Hypothyroidism Premature delivery of a volunteer Discontinue patient cooperation Irregularities in referrals

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Pregnant women with CTS in the third trimester of pregnancy were selected by simple and available sampling and randomly divided into two groups: kinesiotype (n: 15) and group (n: 15). In this study, for random allocation, the coin tossing method was used in such a way that one group is considered a lion and one group is considered a line and the number of coin samples is tossed and individuals are randomly assigned to two groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients did not know the study groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Tehran - Imam Hossein (AS) Square - Damavand St. (New Tehran) - in front of Bouali Hospital - Faculty of Rehabilitation Sciences Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1616913111

Approval date

2017-07-28, 1396/05/06

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.570

Health conditions studied

1

Description of health condition studied

carpal tunnel syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of symptoms

Timepoint

Immediately before and immediately after the intervention

Method of measurement

Boston Questionnaire

2

Description

Functional status

Timepoint

Immediately before and immediately after the intervention

Method of measurement

Boston Questionnaire

3

Description

Transverse cross section of median nerve
Timepoint
Immediately before and immediately after the intervention
Method of measurement
ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the cupping group, air cupping will be used in the anterior region of the hand, and to create a vacuum, a hand pump equipped with a monitor (Gauge) will be used to adjust the pressure in millimeters of mercury. These treatments will be performed for 8 sessions two days a week for a total of 4 weeks. Under the edge of the cup, ultrasound gel without therapeutic properties will be used for better adaptation of the cup for patients.

Category

Rehabilitation

2

Description

In this group, the treatment will be done for 4 weeks, so that in each week, subjects will receive 3 days of kinesiotype as fascia technique. Then they will receive one day without kinesiotype and then another 3 days of kinesiotype. The I-shaped kinesiotype tape will be measured from the proximal palmar fold to the medial epicondyle of the humerus, then a Y-shaped cut will be made on the kinesiotype tape. The patient's elbow and wrist will be extended (complete stretch with the patient's other hand). The base of Y-shaped cut will be attached to the proximal palmar fold and the medial proximal tail will be attached in the direction of the medial epicondyle of the humerus with moderate tension (50% initial tension). Then, another I kinesiotype I tape with technique space with 25% tension will be used for dorsal wrist above the ulnar and radius.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation, Shahid Beheshti University of Medical Science

Full name of responsible person

Sedigheh Sadat Naimi

Street address

Damavand St., in front of Bouali Hospital, Shahid

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Tehran - Shahid Chamran Highway - Yemen Street - next to Taleghani Hospital - Shahid Beheshti University of Medical Sciences

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Web page address

https://isid.research.ac.ir/Afshin_Zarghi

Grant name

Shahid Beheshti University of Medical Science

Grant code / Reference number

-

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

No

Title of funding source

Dr. Afshin Zarghi

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sedighe Sadat Naimi

Position

associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

Contact

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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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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