

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation the effectiveness of Frankincense on symptoms, signs & electrodiagnostic parameters of patients with carpal tunnel syndrome.

Protocol summary

Study aim

Studying the effectiveness of Frankincense on electrodiagnostic study and clinical symptoms in patients with Carpal Tunnel Syndrome .

Design

A concealed, randomized, blinded, sham controlled clinical trial with a parallel group design of 28 samples, enrolled in 2017

Settings and conduct

In all patients admitted to Emam Khomeini PM&R clinics and have inclusion criteria ,electrodiagnostic parameters,VAS for pain severity ,Grip power,Boston questionnaire parameters are measured in both groups before and after intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged ≥ 18 years with unilateral or bilateral mild or moderate CTS; patients who have at least two signs or one sign and one symptom of CTS such as numbness, paresthesia, positive Tinel or Phalen tests; patients who agree to participate in this study. Exclusion criteria: patients with severe CTS; Patients with history of previous surgical release of the carpal tunnel; patient who have intra canal corticosteroids injection in last 6 months; patients with cervical radiculopathy.

Intervention groups

Intervention group: they receive topical Frankincense derived product ,twice a day with standard treatment (cockup splint) for six weeks. Control group: they receive placebo, with the same appearance ,smell and viscosity as the intervention, twice a day with standard treatment (cockup splint) for six weeks.

Main outcome variables

Electrodiagnostic parameters; pain severity based on VAS; Grip power; functional status scale and symptom severity scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180731040647N1**

Registration date: **2019-02-24, 1397/12/05**

Registration timing: **retrospective**

Last update: **2019-02-24, 1397/12/05**

Update count: **0**

Registration date

2019-02-24, 1397/12/05

Registrant information

Name

Seyede Zahra Emami Razavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6119 2291

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z-emamirazavi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-06, 1397/08/15

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effectiveness of Frankincense on symptoms, signs & electrodiagnostic parameters of patients with carpal tunnel syndrome.

Public title

Effect of Frankincense on carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged ≥ 18 years Patients with unilateral or bilateral mild or moderate CTS Patients who have at least two signs or one sign and one symptom of CTS, such as numbness, paresthesia, positive Tinel or Phalen tests patients who agreed to participate in this study

Exclusion criteria:

Patients with severe CTS Patients with history of previous surgical release of the median nerve Patients with sequelae of fracture of the wrist Patient who have intra canal corticosteroids injection in the last 6 months Patients with cervical radiculopathy Patient who have taken analgesics or corticosteroid Patients with any underlying disease such as DM, CRF, neuropathy Alcoholic patients Patients who have allergy to drug or placebo Patients who do not agree to participate or who do not sign the consent form

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **36**

More than 1 sample in each individual

Number of samples in each individual: **2**

hands of the patients with mild or moderate CTS.

Randomization (investigator's opinion)

Randomized

Randomization description

Subject selection will be done by simple randomization among patients with Carpal Tunnel Syndrome, coming to physical medicine & rehabilitation clinics affiliated with Tehran University of Medical Sciences in 2018-2019. Treatment allocation was constructed with table of random numbers. In addition, numbered opaque envelopes used to conceal random sequence.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study is triple blind. The patients, the clinical teams and the people who analyze the data are kept blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran university of Medical Sciences

Street address

Ghods St, Keshavarz Blvd, Tehran Province, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-02-12, 1396/11/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.4487

Health conditions studied**1****Description of health condition studied**

carpal tunnel syndrome

ICD-10 code

G56.0

ICD-10 code description

Mononeuropathies of upper limb, current traumatic nerve disorder, Carpal tunnel syndrome

Primary outcomes**1****Description**

Pain score based on visual analogue scale

Timepoint

Before intervention and 2,6 weeks after intervention

Method of measurement

Visual Analogue Scale

2**Description**

Grip power in affected hand

Timepoint

Before intervention and 2 and 6 weeks after intervention

Method of measurement

hand dynamometry

3

Description

Electrodiagnostic parameters including median sensory and motor nerve conduction studies to determine initial latency and base to peak amplitude are registered.

Timepoint

Before intervention and 2,6 weeks after intervention

Method of measurement

Electrodiagnostic machine.

4

Description

symptom severity scale & functional status scale

Timepoint

Before intervention and 2,6 weeks after intervention

Method of measurement

Boston Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: they go under treatment of topical product, derived from Frankincense ,every other 12 hours for 6 weeks on their volar surface of wrist.they also wear cock up splints as a standard care for mild or moderate carpal tunnel syndrome.

Category

Treatment - Drugs

2

Description

Control group: they go under treatment of placebo, which is completely similar to drug in appearance, color and viscosity ,every other 12 hours ,for 6 weeks on their volar surface of wrist.they also wear cock up splints as a standard care for mild or moderate carpal tunnel syndrome.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex Center

Full name of responsible person

Setareh Rohani Shahraki

Street address

Keshavarz Blvd, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Shahin Akhoundzadeh

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Setareh Rohani Shahraki

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Position

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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

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