Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 petients 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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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 heve 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 cortcosteroid Patients with any undelying 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,urrent 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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1419733141
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Web page address
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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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Email
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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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No. 49 , 7th floor,C2 block, 1st phase ,Ekbatan town,Tehran

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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