Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of effectiveness of topical chamomile oil and placebo in the advancement of Boston questionnaire's score and electrodiagnostic criteria of patients with severe carpal tunnel syndrome

Protocol summary

Summary

This is a randomized, placebo-controlled, triple blinded clinical study to evaluate the effects of topical chamomile oil on the treatment of severe carpal tunnel syndrome.80 hands with primary idiopathic CTS aged between 18-70, after taking signed informed consent, according to the electrodiagnosis classification criteria with clinical picture correlated with CTS, are included in this trial. The main exclusion criteria included: recurrent carpal tunnel syndrome; Positive history of trauma or fracture of wrist bones, surgical release of median nerve, direct injection into carpal tunnel of wrist; Evidence of cervical radiculopathy in EMG; Systemic disease including neuropathies (rule out by nerve conduction study of ulnar nerves), collagen vascular diseases such as SLE, scleroderma and RA; Endocrine disease such as hypothyroidism, DM, and other disease-inducing neuropathy; Situations such as renal failure, alcoholism or poor medical condition; History of recent and ongoing use of corticosteroids or analgesics that could not be discontinued. 80 hands with severe CTS will allocate to two arms by using blocked randomization. Wrist splint is prescribed for both arms. Chamomile oil and paraffin will be given as encoded, innominate bottles with the same shape and color.Both of them are prescribed as 5 drops, morning and night-time doses for 4 weeks. Boston questionnaire score for CTS, at the beginning time and after 4 weeks of trial, will be evaluated, as the primary outcome measure, by a single researcher.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014053011341N3**
Registration date: **2014-06-24, 1393/04/03**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2014-06-24, 1393/04/03

Registrant information

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Mohammad Hashem Hashempur
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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-06-15, 1393/03/25

Expected recruitment end date

2014-12-30, 1393/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of topical chamomile oil and placebo in the advancement of Boston questionnaire's score and electrodiagnostic criteria of patients with severe carpal tunnel syndrome

Public title

Effect of chamomile oil in the treatment of carpal tunnel syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
inclusion criteria: primary idiopathic carpal tunnel syndrome; patients aged between 18-70 years old; electrodiagnostic criteria for severe CTS; Patient's written informed consent for inclusion; having at least two signs or one sign plus one symptom of: paresthesias, numbness, tingling, night pain positive Phalen test, positive Tinnel test, positive compression test. Exclusion criteria: recurrent carpal tunnel syndrome; Positive history of trauma and/or fracture of wrist bones and/or surgical release of median nerve and/or direct injection into carpal tunnel of wrist; Evidence of cervical radiculopathy in EMG; Systemic disease including: neuropathies (rule out by nerve conduction study of ulnar nerves) and/or collagen vascular diseases such as SLE and scleroderma and RA; Endocrine diseases such as hypothyroidism and DM; Other disease-inducing neuropathy; Situations such as renal failure and/or alcoholism and/or poor medical condition; History of recent and ongoing use of corticosteroids or analgesics that could not be discontinued; hypersensitivity to the drug or placebo; inability to completion of data gathering forms (cognitive or language disorder).

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Zand Street.

City
Shiraz

Postal code

Approval date
2014-04-12, 1393/01/23

Ethics committee reference number
CT-P-9365-6205

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
Boston Carpal Tunnel Questionnaire score

Timepoint
beginning of the study and after 4 weeks

Method of measurement
Boston Carpal Tunnel Questionnaire

Secondary outcomes

1

Description
median nerve sensory distal latency

Timepoint
beginning of the study and after 4 weeks

Method of measurement
electrodiagnosis

2

Description
median nerve wrist sensory nerve conduction velocity

Timepoint
beginning of the study and after 4 weeks

Method of measurement
electrodiagnosis

3

Description
median nerve motor distal latency

Timepoint
beginning of the study and after 4 weeks

Method of measurement
electrodiagnosis

4

Description
median nerve compound latency
Timepoint
beginning of the study and after 4 weeks
Method of measurement
electrodiagnosis

5

Description
Compound nerve action potential
Timepoint
beginning of the study and after 4 weeks
Method of measurement
electrodiagnosis

6

Description
Grip power
Timepoint
beginning of the study and after 4 weeks
Method of measurement
dynamometry

7

Description
median nerve sensory proximal latency
Timepoint
beginning of the study and after 4 weeks
Method of measurement
electrodiagnosis

Intervention groups

1

Description
drug: chamomile oil, 5 drops, palmar wrist local use, morning and night-time, 4 weeks with wrist splint with 5 degrees extension for night-time use
Category
Treatment - Drugs

2

Description
placebo:liquid paraffin, 5 drops, palmar wrist local use, morning and night-time, 4 weeks with wrist splint with 5 degrees extension for night-time use
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital
Full name of responsible person
Dr. Zeinab Nasiri
Street address
Iranian Traditional Medicine College, Medicine Faculty, Imam Hossein Square, Zand Street
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Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr.Seyyed Basir Hashemi
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Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Zand Street.
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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
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty