Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

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

Protocol summary

Summary

This is a randomized, placebo-controlled, triple blinded clinical study to evaluate the effects of topical linseed oil on the treatment of mild and moderate carpal tunnel syndrome.100 patients with primary idiopathic CTS aged between 18-65, 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. 100 cases with mild and moderate CTS will allocate to two arms by using blocked randomization. Wrist splint is prescribed for both arms. Linseed 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. Electrodiagnostic classificationat and Boston questionnaire score for CTS, at the beginning time and after 4 weeks of trial, will be evaluated, as the primary outcome measures, by a single researcher.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012103111341N1**
Registration date: **2013-10-19, 1392/07/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-10-19, 1392/07/27

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology of Shiraz University of Medical Sciences

Expected recruitment start date

2013-10-14, 1392/07/22

Expected recruitment end date

2013-12-03, 1392/09/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of topical linseed oil and placebo in the advancement of Boston questionnaire's

score and electrodiagnostic criteria of patients with mild and moderate carpal tunnel syndrome

Public title
Effect of linseed oil in the treatment of carpal tunnel syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: primary idiopathic carpal tunnel syndrome; patients aged between 18-65 years old; electrodiagnostic criteria for mild or moderate 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: Clinical and electrodiagnostic evidence of severe CTS including muscular atrophy and neurogenic changes in needle EMG of APB muscle; 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
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
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 office, Shiraz University of Medical Sciences, Zand street, Shiraz, Iran.
City
Shiraz
Postal code
Approval date
2013-10-08, 1392/07/16
Ethics committee reference number
CT-92-6709

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
median nerve wrist sensory nerve conduction velocity
Timepoint
beginning of the study and after 4 weeks
Method of measurement
electrodiagnosis

2

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

3

Description
median nerve sensory 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

Boston Carpal Tunnel Questionnaire score

Timepoint

beginning of the study and after 4 weeks

Method of measurement

Boston Carpal Tunnel Questionnaire

Secondary outcomes

empty

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

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Gholamreza Haatam

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

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Shiraz

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

Contact

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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