

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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 classification 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

Name

Mohammad Hashem Hashempur

Name of organization / entity

Fasa University of Medical Sciences

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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 Tinel 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.
City
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

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Name of organization / entity
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Postal code**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