

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparing the effect of a topical traditional medicine product based on linseed oil, with standard therapy of medical wrist splint in reducing sensory and functional symptoms of mild to moderate idiopathic carpal tunnel syndrome. - A randomized clinical trial.

Protocol summary

Summary

objective: Comparing the effect of a topical traditional medicine product, with standard therapy of medical wrist splint in reducing sensory and functional symptoms of mild to moderate idiopathic carpal tunnel syndrome. Study Design: Randomized open clinical trial Study population: age group; 20 to 60 years of both sexes. Inclusion criteria: clinical diagnosis; confirmation of diagnosis of mild to moderate CTS with electrodiagnosis report. Exclusion criteria: existence of a history of causing carpal tunnel syndrome, such as wrist trauma, diabetes, thyroid and rheumatologic disease; thenar muscles atrophy; a severe type of CTS in electrodiagnosis report. intervention: the group treated by topical gel and the other one with wrist splint

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112120023N1**
Registration date: **2015-05-12, 1394/02/22**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-05-12, 1394/02/22

Registrant information

Name

Mohammad Setayesh

Name of organization / entity

Tehran University of Medical Science, faculty of traditional medicine

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Government resources: includes credits related to the thesis and research projects of Tehran University of Medical Sciences as well as Kerman University of Medical Sciences, who is doing trial setting and the study and recruitment environment.

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of a topical traditional medicine product based on linseed oil, with standard therapy of medical wrist splint in reducing sensory and functional symptoms of mild to moderate idiopathic carpal tunnel syndrome. - A randomized clinical trial.

Public title

Comparison of therapeutic effects of linseed oil topical gel, with wrist splint in carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients of both sexes in the age range of 20 to 60 years; clinically diagnosed CTS by a specialist; confirmed mild to moderate CTS by electrodiagnosis report; signing the informed consent form and accept the terms of participation in the study. Exclusion criteria: the inability to filling forms (mental disability or speech impairment); history of trauma or surgery in carpal tunnel region or direct injection into the tunnel of carp; pregnancy; history of diabetes and thyroid disorders announced by the patient; median nerve involvement in areas other than the carpal region that is established with the clinical diagnosis and NCV; history of collagen vascular diseases such as rheumatoid arthritis, scleroderma, amyloidosis, lupus and synchronization with other tenosynovitis certified by rheumatologist; history of dermal reaction due to the use of local products; history of allergy to topical or oral compositions of linen; recent cancer chemotherapy and radiotherapy; taking corticosteroids, immunosuppressants and cytotoxic agents; serious medical conditions such as kidney or heart failure or cancer; pathological obesity or leanness (based on BMI); thenar muscle atrophy; permanent paresthesia; severe type of CTS in NCV.

Age

From **20 years** old to **60 years** old

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)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Science

Street address

keshavarz boulevard, Tehran University of Medical Science

City

Tehran

Postal code

Approval date

2015-04-14, 1394/01/25

Ethics committee reference number

9021309002-132293

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

sensory symptoms in CTS

Timepoint

3 week

Method of measurement

standard Boston questionnaire

2

Description

functional status of hand

Timepoint

3 week

Method of measurement

standard Boston questionnaire

Secondary outcomes

1

Description

local side effect of topical gel

Timepoint

first day, end of third week

Method of measurement

history and clinical examination

Intervention groups

1

Description

Intervention group: linseed oil-based topical gel, twice daily, morning and night for three weeks, each time at least in amount of distal phalanx of index finger is gently rubbed on the palmar surface of the wrist, 2-3 cm above and below the wrist joint or joints without massage. Not washed their hands after using the gel for at least one hour.

Category

Treatment - Drugs

2**Description**

standard group: standard CTS splint, only at night for three weeks.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Besat Clinic number 1 - Kerman University of Medical Sciences

Full name of responsible person

Mohammad setayesh

Street address

somayeh crossroads

City

kerman

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Science

Full name of responsible person

Dr. hossein rezaeizade

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Faculty of Traditional Medicine, west. Jamali, Vafamanesh st., Heravi sq., Tehran, Iran

City

Tehran

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 Science

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****Name of organization / entity**

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Full name of responsible person

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Full name of responsible person

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Web page address**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