

# 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)

#### Phone

+98 34 3247 4632

#### Email address

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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

**Street address**

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**

Tehran University of Medical Science

**Full name of responsible person**

Mohammad Setayesh

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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*