

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Efficacy of topical linseed oil on patients with pregnancy-related 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 patients with pregnancy-related carpal tunnel syndrome. Sixty hands with pregnancy-related CTS aged between 18-45 with gestational age 20-32 wk, 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. 60 hands with approved cts will allocate to two arms by using blocked randomization. for the patients in the intervention group the linseed oil products with the size of a pea (depending on the size of the patient, so that the area is completely covered) and 3 times a day (morning, afternoon and night), for use in wrist palmar area, without additional massage is prescribed. The control group will receive placebo with the same method for a period of 4 weeks. Boston questionnaire score for CTS and electrodiagnostic criteria, at the beginning time and after 4 weeks of trial, will be evaluated, by a single researcher.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015110224832N1**

Registration date: **2015-11-27, 1394/09/06**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-11-27, 1394/09/06

##### Registrant information

###### Name

Maryam Nasiri asl

###### Name of organization / entity

Fasa university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 5335 0994

###### Email address

m.nasiri@fums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Fasa University of Medical Sciences

##### Expected recruitment start date

2015-12-22, 1394/10/01

##### Expected recruitment end date

2016-09-20, 1395/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of topical linseed oil on patients with pregnancy-related carpal tunnel syndrome

##### Public title

Efficacy of topical linseed oil on patients with pregnancy-related carpal tunnel syndrome

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: pregnancy-related carpal tunnel syndrome; patients aged between 18-45 years old; electrodiagnostic criteria for mild to 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 Tinel 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

From **18 years** old to **45 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## 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

Fasa University of Medical Sciences

##### Street address

Fasa University of Medical Sciences, Ebne Sina square

## City

Fasa

## Postal code

## Approval date

2015-11-09, 1394/08/18

## Ethics committee reference number

IR.FUMS.REC.1394.27

## 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

At the 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

At the beginning of the study and after 4 weeks

#### Method of measurement

Electrodiagnosis

### 2

#### Description

Median nerve wrist sensory nerve conduction velocity

#### Timepoint

At the beginning of the study and after 4 weeks

#### Method of measurement

Electrodiagnosis

### 3

#### Description

Median nerve motor distal latency

#### Timepoint

At the beginning of the study and after 4 weeks

#### Method of measurement

Electrodiagnosis

### 4

#### Description

Median nerve compound latency

**Timepoint**

At the beginning of the study and after 4 weeks

**Method of measurement**

Electrodiagnosis

**Intervention groups****1****Description**

Linseed oil products, with the size of a pea (depending on the size of the patient, so that the area is completely covered) and 3 times a day (morning, afternoon and night), for use in wrist palmar area, without additional massage for 4 weeks

**Category**

Treatment - Drugs

**2****Description**

Base of moisturizing gel, with the size of a pea (depending on the size of the patient, so that the area is completely covered) and 3 times a day (morning, afternoon and night), for use in wrist palmar area, without additional massage for 4 weeks.

**Category**

Placebo

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

Valiasr clinic

**Full name of responsible person**

Dr. Fereshteh Kalhori

**Street address**

Valiasr hospital, Ebne sina square

**City**

Fasa

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

Fasa University of Medical Sciences

**Full name of responsible person**

Dr. Ehsan Bahramali

**Street address**

Fasa University of Medical Sciences, Ebne Sina square

**City**

Fasa

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Fasa 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****Name of organization / entity**

Fasa University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Askari

**Position**

Assistant professor of orthopaedics

**Other areas of specialty/work****Street address**

Fasa University of Medical Sciences, Ebne Sina square

**City**

Fasa

**Postal code****Phone**

+98 71 5335 0994

**Fax****Email**

aaskari@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Fasa University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Hashem Hashempur

**Position**

PhD of traditional Medicine

**Other areas of specialty/work****Street address**

Fasa University of Medical Sciences, Ebne Sina square

**City**

Fasa

**Postal code****Phone**

+98 71 5335 0994

**Fax****Email**

hashempur@gmail.com

**Web page address****Person responsible for updating data****Contact**

**Name of organization / entity**

Fasa University of Medical Sciences

**Full name of responsible person**

Maryam Nasiri Aasl

**Position**

Medical student

**Other areas of specialty/work****Street address**

Fasa University of Medical Sciences, Ebne Sina square

**City**

Fasa

**Postal code****Phone****Fax****Email**

m.nasiri@fums.ac.ir

**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*