Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
m-setayesh@razi.tums.ac.ir

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 linseedd 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
Position
Phd candidate in Traditional Medicine in Tehran University of Medical Science
Other areas of specialty/work
Street address
Faculty of Traditional Medicine, west. Jamali, Vafamanesh st., Heravi sq., Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 2298 8551
Fax
Email
m-setayesh@razi.tums.ac.ir
msetayeshmail@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Science
Full name of responsible person
Mohammad Setayesh
Position
Phd candidate of Traditional Medicine in Tehran University of Medical Science
Other areas of specialty/work
Street address
Faculty of Traditional Medicine, west. Jamali, Vafamanesh st., Heravi sq., Tehran, Iran
City
Tehran
Postal code
Phone
+212 29885512
Fax
Email
m-setayesh@razi.tums.ac.ir
msetayeshmail@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Science
Full name of responsible person
Mohammad Setayesh
Position
Phd candidate of Traditional Medicine in Tehran University of Medical Science
Other areas of specialty/work
Street address
Faculty of Traditional Medicine, west. Jamali, Vafamanesh st., Heravi sq., Tehran, Iran

City
Tehran
Postal code
Phone
+212 29885512
Fax
Email
msetayesh@razi.tums.ac.ir
msetayeshmail@gmail.com
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