Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Efficacy of topical curcumin on mild to moderate Idiopathic carpal tunnel syndrome: a randomized double-blind placebo controlled clinical trial

Protocol summary

Study aim
Comparison the effect of Curcumin with placebo on reducing pain intensity in patients with mild to moderate idiopathic carpal tunnel syndrome, in terms of age, body mass index, duration of illness, in reducing paresthesia, efficacy on the electrodiagnostic parameters

Design
Double-blind randomized clinical trial with control group and parallel

Settings and conduct
In the university clinic (Tooba), electrodiagnistic study was performed for all patients selected before treatment and the Boston Questionnaire is filled for them. Patients are evaluated 8 weeks after treatment. All patients and the physician assessing are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: female patients aged 18-65 years old; sign and symptoms of carpal tunnel syndrome: at least two symptoms or one symptom and one sign including: electrodiagnostic evidence suggestive of mild to moderate idiopathic carpal tunnel syndrome. Exclusion criteria: positive history of the curcumin hypersensitivity; cervical radiculopathy or brachial plexopathy; TOS, rotator teres syndrome, ulnar neuropathy clinical polyneuropathy rheumatologic disorders such as: rheumatoid arthritis, systemic sclerosis, lupus, amyloidosis and so on; endocrine disorders: diabetes, hypothyroid, conditions that mimic carpal tunnel syndrome; pregnancy and lactation; serious cardiovascular disease and kidney disease; intravenous injection at wrist over the past 6 months; a positive history of a fracture of the wrist; use of corticosteroids or analgesic drugs.

Intervention groups
The case group used topical curcumin and the control group used placebo

Main outcome variables
Reduced pain, reduced paresthesia, improved electrodiagnostic changes

General information

Reason for update

Acronym
CTS: carpal tunnel syndrome

IRCT registration information
IRCT registration number: **IRCT20140221016666N3**
Registration date: **2019-01-19, 1397/10/29**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-19, 1397/10/29**
Update count: **0**

Registration date
2019-01-19, 1397/10/29

Registrant information

Name
Narges Karimi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3311 6275

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-10-22, 1398/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of topical curcumin on mild to moderate Idiopathic carpal tunnel syndrome: a randomized double-blind placebo controlled clinical trial

Public title
Efficacy of topical curcumin on mild to moderate idiopathic carpal tunnel syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Female patients aged 18-65 years old completed the informed consent form Sign and symptoms of carpal tunnel syndrome: at least two symptoms or one symptom and one sign including: pain, paresthesia, hypoesthesia, numbness, positive phalen or tinel test Electrodiagnostic evidence suggestive of mild to moderate idiopathic carpal tunnel syndrome

Exclusion criteria:
Positive history of the curcumin hypersensitivity Failure to complete the information collection form Cervical radiculopathy or brachial plexopathy, TOS,Protator teres syndrome, ulnar neuropathy Clinical Signs or Electrodiagnostic evidence of Polyneuropathy Rheumatologic disorders such as: rheumatoid arthritis, systemic sclerosis, Lupus, Amyloidosis and so on Endocrine disorders: Diabetes, hypothyroid Conditions that mimic carpal tunnel syndrome, such as multiple sclerosis Pregnancy and lactation Serious cardiovascular disease like heart failure and kidney disease Intravenous injection or physiotherapy for the treatment of carpal tunnel syndrome over the past 6 months A positive history of a severe trauma or fracture of the wrist The inevitable use of corticosteroids or analgesic drugs Patients with severe carpal tunnel syndrome based on clinical or electrodiagnostic evidence

Age
From **18 years** old to **65 years** old

Gender
Female

Phase
1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
The case group uses the topical curcumin form two times daily, and the placebo is given to the control group. Sample selection based on Simple Block Randomized.All patients should avoid doing activities that require Extention and Flexion wrists.Medications and placebo make the Nanocin Healthcare company. Both are in the tubes of the same shape and have the same color and density. Both groups use night-time splint, and medications are used once in the morning and once in the evening. The course is for eight weeks and all patients are evaluated at the end of the eighth week. To evaluate patients from the Visual Analog Scale (VAS) and Boston's questionnaire are used. All results are recorded by the neurologist, which is Blind.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and assessors are blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Sceinces

Street address
Joibar Three ways, Valiasr blvd, Sari city

City
Sari

Province
Mazandaran

Postal code
4818734619

Approval date
2018-07-08, 1397/04/17

Ethics committee reference number
IR.MAZUMS.REC.1397.160

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 questionnaire score and severity of pain according to VAS

Timepoint
Before intervention and Eighth week after treatment

Method of measurement

Boston questionnaire and VAS

2

Description
EMG-NCV parameters changes
Timepoint
Before intervention and Eighth week after treatment
Method of measurement
Electrodiagnostic

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Curcumin topical ointment is a turmeric extract and is manufactured by Exir Nanosina.Twice a day in the morning and at the night, 12 hours interval, in the anterior of wrist is rubbed. duration of treatment is 8-week.The ointment should not be washed up to 2 hours after using the ointment.
Category
Treatment - Drugs

2

Description
Control group: The placebo is an ointment that has a shape, color and concentration similar to curcumin ointment. The tubes are in the same shape.Produced by Exir Nanosina company.The frequency of use, dose and duration of use is the similar to intervention group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baghban clinic (medical university clinic)
Full name of responsible person
Narges Karimi
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Baghban Clinic, Khazar Blvd, Sari City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sari University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Narges Karimi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only the part of the data about the main of outcome will be shared
When the data will become available and for how long
the access period is 6 months after publishing the results
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
Only for scientific use
From where data/document is obtainable
Narges Karimi Email: Drkarimi_236@yahoo.com
What processes are involved for a request to access data/document
Noting the reason for requesting and identifying the type of applicant institution Email: Drkarimi_236@yahoo.com After review and, if possible, the data will be sent
Comments