Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of local corticosteroid injection and high-intensity laser outcomes in moderate carpal tunnel syndrome (CTS)

Protocol summary

Study aim

The results of this study indicate the clinical implications of treatment modalities of moderate carpal tunnel syndrome, and it is undoubtedly important to prove these differences clinically, enabling researchers to employ more appropriate therapeutic approaches than the economic burden imposed. Reduce the burden on society and patients and provide the least complications and best outcomes for patients.

Design

A concealed, randomized, open-label, sham-controlled clinical trial with a parallel-group design of 126 patients.

Settings and conduct

Patients are referred daily to Imam Reza Clinic of Poursina Hospital and if they have the inclusion criteria, 42 patients in each group will be enrolled in the study based on randomized block design with a total of 126 patients. Patients will be randomly divided into three treatment groups.

Participants/Inclusion and exclusion criteria

Patients with unilateral or bilateral CTS will be enrolled. Patients will be excluded if they have a history of wrist surgery, polyneuropathy, brachial plexopathy or thoracic outlet syndrome, history of thrombocytopenia, platelet disorder, systemic infection, pregnancy, and rheumatologic disorders, previous injection of cortisone for the treatment of CTS, Thenar muscle atrophy.

Intervention groups

Control group: The control group will be given splint with a painkiller (meloxicam 15 mg) and vitamin B1. Group 2, 40 mg methylprednisolone (Depo-Medrol) in combination with 1% lidocaine will be injected. Group 3 in order to laser therapy, the patient in a supine position will be irradiated to an area of 4 x 5 cm area around the nerve. The scanner laser will be illuminated from a distance of 10 cm.

Main outcome variables

Pain severity; Distal sensory delay; Distal motor delay; Symptom severity scale; Functional status scale; complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200219046552N1**
Registration date: **2020-03-29, 1399/01/10**
Registration timing: **prospective**

Last update: **2020-03-29, 1399/01/10**
Update count: **0**

Registration date

2020-03-29, 1399/01/10

Registrant information

Name

Mozaffar Hosseininezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3378 1132

Email address

mhosseininezhad@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of local corticosteroid injection and high-intensity laser outcomes in moderate carpal tunnel syndrome (CTS)

Public title
Comparison of local corticosteroid injection and high-intensity laser outcomes in moderate carpal tunnel syndrome (CTS)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with unilateral or bilateral CTS according to Median Nerve Electrophysiology (EMG-NCV) studies will be enrolled.

Exclusion criteria:
History of wrist surgery, polyneuropathy, brachial plexopathy or thoracic outlet syndrome History of thrombocytopenia, platelet disorder, systemic infection, pregnancy and rheumatologic disorders. Previous injection of cortisone for treatment of CTS Thenar muscle atrophy

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly divided into 42 groups in each group and 126 in the Random Allocation software. The format will be in a sealed envelope at the Neuroscience Research Center under the supervision of the inspector. On a daily basis, patients will be studied in groups.

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
Ethics committee of Guilan University of Medical Sciences

Street address
Namjoo st., Poursina Hospital

City
Rasht

Province
Guilan

Postal code
41937-13194

Approval date
2019-12-21, 1398/09/30

Ethics committee reference number
IR.GUMS.REC.1398.435

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
Symptom severity scale in Boston Carpal Tunnel Syndrome Questionnaire

Timepoint
Measurement of symptom severity at baseline and 6 months later.

Method of measurement
Boston Carpal Tunnel Syndrome Questionnaire

2

Description
Functional status scale in Boston Carpal Tunnel Syndrome Questionnaire

Timepoint
Measurement of functional status at baseline and 6 months later.

Method of measurement
Boston Carpal Tunnel Syndrome Questionnaire

Secondary outcomes

1

Description
Severity of pain

Timepoint
At baseline and 6 months after intervention.

Method of measurement
Visual analog scale

2

Description
Distal sensory latency
Timepoint
At baseline and 6 months after intervention.
Method of measurement
Based on the amount recorded by the EMG-NCV device.

3

Description
Distal motor latency
Timepoint
At baseline and 6 months after intervention.
Method of measurement
Based on the amount recorded by the EMG-NCV device.

4

Description
medical complications
Timepoint
6 months after intervention
Method of measurement
Based on individual response

Intervention groups

1

Description
Control group: The splint will be prescribed with painkillers (meloxicam 15 mg) and vitamin B1. The splint should be used in neutral position for at least 8 hours a day for 3 months (night and during activity) and painkillers and Vitamin B1 will be taken daily for 6 weeks.
Category
Treatment - Devices

2

Description
First intervention group: 40 mg of methylprednisolone (depromedrol) in combination with 1% lidocaine will be injected with a 23G needle so that the needle will be placed on the inner side of the Palmaris longus tendon in the distal palmar groove at an angle of 45 ° to the forearm.
Category
Treatment - Drugs

3

Description
Second intervention group: In order to perform laser therapy, the patient is cleaned in a supine position with a cotton swab. It will then be irradiated as much as 4 x 5 cm around the nerve and the laser scanner will be illuminated from a distance of 10 cm. The laser therapy time for each area will be 167 seconds. It should be noted that the laser rotation will be zero, 60% Duty cycle and 100 Hz frequency. Each patient will undergo laser therapy for 3 sessions, one day in between.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Poursina hospital
Full name of responsible person
Mozaffar Hosseininezhad
Street address
Namjoo st., Rasht Town
City
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Guilan
Postal code
41937-13194
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hosseininezhadm@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Research Technology deputy
Street address
Deputy of university Research and Technology of the University, Old Bldg (building) School of Health, in front of 17 Shahrivar Hospital, Shahid Siadati Ave., Namjoo St.
City
Rasht
Province
Guilan
Postal code
66949-41446
Phone
+98 13 3333 5820
Email
nemati@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Mozaffar Hosseininezhad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mozaffar Hosseininezhad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mozaffar Hosseininezhad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Phone

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

A portion of the study participants' personal data, including demographic data and study outcomes, will be shared after unidentifiable individuals.

When the data will become available and for how long

The access period will start 3 months after printing.

To whom data/document is available

Researchers working in universities.

Under which criteria data/document could be used

Researchers working in universities.

From where data/document is obtainable

Address: Poursina Hospital, Namjoo st., Rasht

What processes are involved for a request to access

data/document

A written request for data from the relevant university with the name and academic degree of the researcher

Comments