Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Compare the effect of ozone injection with corticosteroid injection on carpal tunnel syndrome

Protocol summary

Study aim

compare the effect of ultrasound guided corticosteroid injection with ozone injection in patients with carpal tunnel syndrome.

Design

in this study forty patients with carpal tunnel syndrome referred to Firuzgar physical medicine and rehabilitation clinic, Tehran, Iran will be included in the study after qualifying the inclusion and exclusion criteria and obtaining the informed consent . (3) Setting and conduct: patients will be randomly divided to two groups of twenty. For randomization we will use randomized blocking method. (4) Interventions: ultrasound-guided local injection of forty mg of triamcinolone with the in-plane method; in the first group around the median nerve and in t in another group under sterile conditions, 3 cc oxygen ozone (O2O3), (10 mg / ml) under ultrasound guided to the median nerve will be done by a physical medicine and rehabilitation specialist. Routine treatments including wrist splint for 6 weeks will be performed for all patients. (5) Main outcome measures: electrodiagnostical and sonographic criteria, Boston questionnaire scores and VAS will be assessed in the 0, 6th week and 12th weeks.

Settings and conduct

in this study forty patients with carpal tunnel syndrome referred to Firuzgar physical medicine and rehabilitation clinic, Tehran, Iran will be included in the study after qualifying the inclusion and exclusion criteria and obtaining the informed consent . (3) Setting and conduct: patients will be randomly divided to two groups of twenty. For randomization we will use randomized blocking method. (4) Interventions: ultrasound-guided local injection of forty mg of triamcinolone with the in-plane method; in the first group around the median nerve and in t in another group under sterile conditions, 3 cc oxygen ozone (O2O3), (10 mg / ml) under ultrasound guided to the median nerve will be done by a physical medicine and rehabilitation specialist. Routine treatments including wrist splint for 6 weeks will be performed for all patients. (5) Main outcome measures: electrodiagnostical and sonographic criteria, Boston questionnaire scores and VAS will be assessed in the 0, 6th week and 12th weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with signs and symptoms of carpal tunnel syndrome (including pain and sensory disturbances in the territory of median nerve) which is confirmed through EMG-NCS and by electrodiagnostic criteria are mild to moderate carpal tunnel syndromes. Exclusion criteria: severe carpal tunnel syndrome in EMG-NCV; tenar atrophy; contraindications for corticosteroid injection (including sensitivity to corticosteroids and symptoms of skin infection at the injection site); diseases which mimic CTS symptoms such as polyneuropathy, cervical radiculopathy, thoracic outlet syndrome; surgery or local injection treatments in last six months; neoplastic or traumatic source of pain; wrist bones fracture.

Intervention groups

In the first group,corticosteroid inject under the ultrasound-guid around the median nerve which will be done by an experienced physical medicine and rehabilitation specialist using in-plane approach In the first group, ozon inject under the ultrasound-guid around the median nerve which will be done by an experienced physical medicine and rehabilitation specialist using in-plane approach

Main outcome variables

The severity of symptoms and functional limitations by Boston questionnare The severity of symptoms by Visual Analog Scale(VAS) Electrodiagnostic criteria by using EMG-NCV device Sonographic criteria by using Sonographic device Side effects by questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151017024572N5**
Registration date: **2017-12-28, 1396/10/07**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-28, 1396/10/07**
Update count: **0**

Registration date
2017-12-28, 1396/10/07

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-12-27, 1396/10/06
Expected recruitment end date
2018-04-26, 1397/02/06
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Compare the effect of ozone injection with corticosteroid injection on carpal tunnel syndrome

Public title
Compare the effect of ozone injection with corticosteroid injection on carpal tunnel syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients with signs and symptoms of carpal tunnel syndrome (including pain and sensory disturbances in the territory of median nerve) which is confirmed through EMG-NCS and by electrodiagnostic criteria are mild to moderate carpal tunnel syndromes.
Exclusion criteria:
severe carpal tunnel syndrome in EMG-NCV tenar atrophy contraindications for corticosteroid injection (including sensitivity to corticosteroids and symptoms of skin infection at the injection site) diseases which mimic CTS symptoms such as polyneuropathy, cervical radiculopathy, thoracic outlet syndrome; surgery or local injection treatments in last six months; neoplastic or traumatic source of pain; wrist bones fracture.
Age
From **20 years** old to **80 years** old
Gender
Both
Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization using random numbers table
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants are unaware of their injection substance. A person completing questionnaires and collecting information will be unaware of the type of injection substance. The information analyst will also be unaware of the treatment groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی ایران
Street address
Ethics committee, Iran University of Medical Sciences, Hemmat Highway, Tehran
City
tehran
Province
Tehran
Postal code
1449614535
Approval date
2017-12-26, 1396/10/05
Ethics committee reference number
IR.IUMS.FMD.REC 1396.9411524006

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

The severity of symptoms and functional limitations

Timepoint

Zero, six and twelve weeks after

Method of measurement

By using Boston questionnare

2

Description

The severity of symptoms

Timepoint

Zero, six and twelve weeks after

Method of measurement

Visual Analog Scale(VAS)

3

Description

Electrodiagnostic criteria

Timepoint

Zero, six and twelve weeks after

Method of measurement

By using EMG-NCV device

4

Description

Sonographic criteria

Timepoint

Zero, six and twelve weeks after

Method of measurement

By using Sonographic device

Secondary outcomes

1

Description

Side effects

Timepoint

Six and twelve weeks after

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: ozon injection under the ultrasound-guid around the median nerve which will be done by an experienced physical medicine and rehabilitation specialist

Category

Treatment - Drugs

2

Description

Control group: corticosteroid injection under the ultrasound-guid around the median nerve which will be done by an experienced physical medicine and rehabilitation specialist

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firuzgar hospital

Full name of responsible person

hosein mohamadi

Street address

Department of Physical Medicine and Rehabilitation, Firuzgar Hospital, Valiasr Square, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Motovalian

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Grant name

Vice President of Research Iran University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
hosein mohamadi
Position
Resident of Physical Medicine and Rehabilitation
Latest degree
Medical doctor
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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Information on the main outcome
When the data will become available and for how long
Start the access period 6 months after printing 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

Confirming the responsible person

From where data/document is obtainable

dr. hosein mohamadi dr.mohamadi89@gmail.com

What processes are involved for a request to access data/document

request by email

Comments