

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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 questionnaire 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
Arash Babaei-Ghazani
Name of organization / entity
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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 questionnaire

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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2564614642

Phone

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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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5th floor, Headquarters, Iran University of Medical Sciences, Hemmat Highway, Tehran

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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

Physical Medicine

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Department of Physical Medicine and Rehabilitation,
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Dr. Arash Babaei

Position

Associate Professor of Physical Medicine and
Rehabilitation

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Street address

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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

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