Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effectiveness of local corticosteroid injection and local ozone injection in patients with carpal tunnel syndrome (CTS)

Protocol summary

Study aim
Comparison of the effectiveness of local corticosteroid injection and local ozone injection in patients with carpal tunnel syndrome (CTS)

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, 42 patients, Randomized by block random method

Settings and conduct
Location: Physical Medicine and Rehabilitation Clinic of Shahid Sadoughi Hospital, Yazd Intervention: 21 patients in group 1 (treated with triamcinolone): injection of 40 mg of triamcinolone plus 1 ml of 1% lidocaine with ultrasound guidance around the median nerve and use of wrist splint for eight weeks 21 patients in group 2 (ozone treatment): 4 cc of ozone with a concentration of 10 mg plus 1 ml of 1% lidocaine with ultrasound guidance around the median nerve and using a splint wrist for eight weeks

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) Patients over 18 years 2) Patients with signs and symptoms of CTS approved by EMG-NCS and with mild to moderate severity based on electrodiagnostic criteria Exclusion Criteria: 1) Perform previous interventions (such as the history of injections, use of splints in the past six months, or any surgery on the carpal tunnel) up to six months before the intervention 2) History of underlying diseases such as diabetes, rheumatoid arthritis, etc 3) Patients treated with ACE-I drugs 4) Patients with severe CTS

Intervention groups
Group 1: Corticosteroid injection Group 2: Ozone injection (both under ultrasound guidance around the median nerve by a physical medicine and rehabilitation specialist)

Main outcome variables
Severity of symptoms and functional limitations by Boston questionnare Severity of symptoms by VAS. Electrodiagnostic criteria by EMG-NCV Sonographic criteria by Sonographic device Side effects by questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210920052535N1**
Registration date: **2022-06-26, 1401/04/05**
Registration timing: **retrospective**

Last update: **2022-06-26, 1401/04/05**
Update count: **0**

Registration date
2022-06-26, 1401/04/05

Registrant information

Name
Farnaz Hesam

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2021-06-10, 1400/03/20

Actual recruitment start date
2021-05-24, 1400/03/03

Actual recruitment end date
2021-06-17, 1400/03/27

Trial completion date
2021-08-11, 1400/05/20

Scientific title
Comparison of the effectiveness of local corticosteroid injection and local ozone injection in patients with carpal tunnel syndrome (CTS)

Public title
Comparison of the effectiveness of ozone and corticosteroid injections in the treatment of CTS

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients over 18 years with signs and symptoms of carpal tunnel syndrome confirmed by Electrodiagnostic study and have mild to moderate CTS according to it.

Exclusion criteria:
Age under 18 years Severe carpal tunnel syndrome Presence of underlying diseases such as diabetes, rheumatoid arthritis, thyroid disease and previous history of trauma Presence of thenar atrophy and peripheral nerve lesions of the upper extremity, polyneuropathy and radiculopathy Pregnancy, history of G6PD deficiency, thrombocytopenia, severe cardiovascular instability, people are receiving ACE-I History of injection or using a splint during the past 6 months or any previous surgery on the carpal tunnel

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **46**
Actual sample size reached: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization was applied. In this method, patients were randomly divided into two groups using a table of random numbers by computer and online (using the site www.random.org/integres)

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, the person who is completing the questionnaires and collecting the information, the person analyzing the information will be unaware of the group therapy and the type of injected substance

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Medicine-Shahid Sadoughi University of Medical Sciences

Street address
Central building of Yazd University of Medical Sciences, Bahonar Sq, Yazd

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Yazd

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Approval date
2021-05-19, 1400/02/29

Ethics committee reference number
IR.SSU.MEDICINE.REC.1400.099

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 and 8th week

Method of measurement
Boston questionnaire was applied

2

Description
The severity of symptoms

Timepoint
Zero and 8th week

Method of measurement
Visual Analog Scale(VAS)

3

Description

Electrodiagnostic criteria

Timepoint

Zero and 8th week

Method of measurement

EMG-NCS device was applied

4

Description

Sonographic criteria

Timepoint

Zero and 8th week

Method of measurement

Sonographic device was applied

Secondary outcomes

1

Description

Side effects

Timepoint

8th week

Method of measurement

Questionnaire

Intervention groups

1

Description

First Intervention group: corticosteroid (40mg Triamcinolone) injection under the ultrasound-guide around the median nerve.

Category

Treatment - Drugs

2

Description

Second Intervention group: ozone (Ozone at a concentration of 10 micrograms per ml with 1 ml of 1% lidocaine) injection under the ultrasound-guide around the median nerve.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital, Yazd

Full name of responsible person

Farnaz Hesam

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Sponsors / Funding sources

1

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Grant name

Vice President of Research Yazd University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Farnaz Hesam

Position
Resident of Physical Medicine and Rehabilitation

Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

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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 Farnaz Hesam f.hesam@rocketmail.com

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

Comments