

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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 questionnaire 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

Country

Iran (Islamic Republic of)

Phone

+98 31 3651 6689

Email address

f.hesam@rocketmail.com

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

City

Yazd

Province

Yazd

Postal code

۸۹۱۶۹۷۸۴۷۷

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
Street address
Ebne Sina St, Shahid Ghandi Blvd, Safaieh, Yazd
City
Yazd
Province
Yazd

Postal code
۸۹۱۵۸۸۷۸۵۷
Phone
+98 35 3822 4000
Fax
+98 35 3822 4100
Email
f.hesam@rocketmail.com
Web page address
<https://ssu.ac.ir>

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud Mirzaei
Street address
Central building of Yazd University of Medical Sciences, Bahonar Sq, Yazd
City
Yazd
Province
Yazd
Postal code
۸۹۱۶۹۷۸۴۷۷
Phone
+98 35 3146 2150
Email
f.hesam@rocketmail.com
Web page address
<https://ssu.ac.ir>
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

Street address

Ebne Sina St, Shahid Ghandi Blvd, safaieh, Yazd

City

Yazd

Province

Yazd

Postal code

۸۹۱۵۸۸۷۸۵۷

Phone

+98 35 3822 4000

Email

f.hesam@rocketmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amidodin khatibi Aghda

Position

Associate Professor of Physical Medicine and Rehabilitation

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Ebne Sina St, Shahid Ghandi Blvd, Safaieh, Yazd

City

Yazd

Province

Yazd

Postal code

۸۹۱۵۸۸۷۸۵۷

Phone

+98 35 3822 4000

Email

dr.khatibi_2@yahoo.com

Person responsible for updating data

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

Street address

Ebne Sina St, Shahid Ghandi Blvd, Safaieh, Yazd

City

Yazd

Province

Yazd

Postal code

۸۹۱۵۸۸۷۸۵۷

Phone

+98 35 3822 4000

Email

f.hesam@rocketmail.com

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