

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Study of the effects of ozone injection in women with mild and moderate Carpal Tunnel Syndrome in physical medicine and rehabilitation clinic

Protocol summary

Summary

This single blind Randomized Clinical Trial was designed to indicate the effects of ozone injection in women with idiopathic mild to moderate Carpal Tunnel Syndrome. A total of 40 patients will be randomly assigned into 2 groups, group A and group B. Group A was treated with a single injection of 4 ml of ozone plus 1ml lidocaine 1%. Both groups used prefabricated hand wrist splint for CTS for 8 weeks. Pain visual analog scale (VAS), (BQ-SYMPT) Bostone/Levine symptom severity scale and Bostone/Levine functional status scale(BQ-FUNC) and EDX studies will be assessed before intervention, 10 weeks and 6 months after the intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040913442N9**
Registration date: **2016-07-14, 1395/04/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-14, 1395/04/24

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 1112

Email address

a_raeissadat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-06-15, 1395/03/26

Expected recruitment end date

2016-10-15, 1395/07/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effects of ozone injection in women with mild and moderate Carpal Tunnel Syndrome in physical medicine and rehabilitation clinic

Public title

Effects of ozone injection in treatment of women with mild and moderate carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient with mild and moderate CTS confirmed by the presence of one or more of the following standard electrophysiological criteria: 1- prolonged distal motor latency (DML) (abnormal ≥ 4.2 ms) of Median nerve and 2- prolonged antidromic distal sensory latency (DSL) to the third digit (abnormal > 3.6 ms; age between 20 to 65 years old. Exclusion criteria: Pregnancy; Severe degree CTS; Background metabolic diseases such as: diabetes mellitus; hypothyroidism; rheumatoid arthritis; Previous history of corticosteroid injection in Carpal Tunnel Syndrome; Severe atrophy of tenar muscles; cervical radiculopathy or significant polyneuropathy; Unwillingness to participate in the present study; patient younger than 20 or older than 65

years old. G6PD

Age
From **20 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committe of faculty of Medicine, Shahid Beheshti University of Medical sciences

Street address
Shahid Beheshti University of Medical sciences, next to Taleghani Hospital, yaman street, Chamran Highway

City
Tehran

Postal code

Approval date
2016-06-10, 1395/03/21

Ethics committee reference number
IR.SBMU.MSP.REC.1395.116

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
pain

Timepoint
0, 10 weeks, 6 months

Method of measurement
Visual Analog Scale, that is from 0-10 and zero (0) means that you did not have any pain and ten (10) means that you had the worst pain imaginable

2

Description
Functional Status

Timepoint
0, 10 weeks, 6 months

Method of measurement
Bostone/levine Functional Status Scale Questionnare

3

Description
Symptome Severity (pain and paresthesia)

Timepoint
0,10 weeks, 6 months

Method of measurement
Bostone/levine Symptome Severity Scale Questionnare

4

Description
Distal Sensory Peak Latency (SNAP) of median nerve

Timepoint
0,10 weeks, 6 months

Method of measurement
EDX Indexes

5

Description
Distal Motor Onset Latency (CMAP) of median nerve

Timepoint
0,10 weeks, 6 months

Method of measurement
EDX indexes

Secondary outcomes

empty

Intervention groups

1

Description
Single injection of 4 ml of ozone with 5 cc syringe and prefabricated hand wrist splint in neutral position (0-5 extension) for CTS for 8 weeks

Category
Treatment - Drugs

2

Description

Prefabricated hand wrist splint in neutral position (0-5 extension) for CTS for 8 weeks

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Modarres hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Science

Full name of responsible person

Seyed Ahmad Raeissadat

Street address

Shahid Beheshti University of Medical sciences, next to Taleghani Hospital, yaman street, Chamran Highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Modarres hospital

Full name of responsible person

Mohammadrasoul nezamabadi

Position

Physical medicine and rehabilitation assistant

Other areas of specialty/work

Street address

Shahid Modarres hospital, Kaj square, Saadat abad street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Modarres Hospital

Full name of responsible person

Seyed Ahmad Raeissadat

Position

Associate professor of PM& R

Other areas of specialty/work

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Email

a_raeissadat@sbmu.ac.ir

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty