

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Sono-guided Oxygen-ozone and corticosteroid therapy for the treatment of musculoskeletal Pain in physical and rehabilitation medicine: Interventional pain management for Carpal tunnel syndrom: A prospective, randomized, double-blind, Multicente

Protocol summary

Study aim

The effect of topical corticosteroid and ozone injection under ultrasound guidance in the treatment of carpal tunnel syndrome

Design

A phase 3, umulticentral, randomized, positive controlled, double blinded, clinical trial with a parallel group design of 50 patients, followed up one week and two months after injection

Settings and conduct

Department of Physical Medicine and Rehabilitation of Shohada Hospital and Imam Reza Hospital affiliated to Tabriz University of Medical Sciences and Physiotherapy and Rehabilitation Physics Department of Rasoul Akram Medical Center affiliated to Iran University of Medical Sciences

Participants/Inclusion and exclusion criteria

Having moderate or Severe moderate carpal tunnel syndrome confirmed by Electrodiagnosis (EDX) criteria, Unwillingness to undergo surgery; The presence of symptoms of severe atrophy or severe CTS in EMG-NCV, Contraindications for corticosteroid injection, Treatment of CTS with surgery or corticosteroid injection in the last 6 months, Traumatic or neoplastic origin of symptoms, Not having satisfaction for injection.

Intervention groups

Topical ozone injection group: 2cc ozone 20µg/L
Corticosteroid injection group: 1cc triamcinolone 40mg + 1cc normal slain

Main outcome variables

Visual Analogue Scale Boston scale

General information

Reason for update

Acronym

PMR

IRCT registration information

IRCT registration number: **IRCT20151017024572N15**

Registration date: **2018-06-04, 1397/03/14**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-04, 1397/03/14**

Update count: **0**

Registration date

2018-06-04, 1397/03/14

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences and Iran University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Sono-guided Oxygen-ozone and corticosteroid therapy for the treatment of musculoskeletal Pain in physical and rehabilitation medicine: Interventional pain management for Carpal tunnel syndrom: A prospective, randomized, double-blind, Multicente

Public title

The effect of Oxygen-ozone and corticosteroid therapy for the treatment of Carpal tunnel syndrom

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Cavernous carpal tunnel syndrome confirmed by Electrodigenesis (EDX) criteria Severe moderate carpal tunnel syndrome that is proven by EDX criteria The presence of paresthesia or numbness in the median nerve pathway Unwillingness of the patient to undergo surgery SNAP amplitude decrease NCV across wrist smaller than 40 m/sec Peak SNAP latency larger than 3.6 msec CMAP latency larger than 4.2 msec

Exclusion criteria:

The presence of severe atrophic symptoms or severe CTS in EMG-NCV. Contraindications for corticosteroid injection such as corticosteroid allergy and injection site infections CTS treatment with surgery or corticosteroid injection in the last 6 months Traumatic or neoplastic origin of symptoms Not having satisfaction for injection CMAP amplitude absence (CMAP) or the presence of symptoms of fib / psw in tense muscles Signs of Cervical Activated Radiculopathy in Nidal Electromigraphy or Extruded Cervical Discs in MRI

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

A simple random method for randomization will be used and individuals (patients) will form random units. A random sequence will be generated using RAS software. A central randomization method will be used to conceal random allocation. The random sequence will be created by the statistician and will be available to her. The doctor will be connected to the statistician by telephone or text message and will ask him or her about the random allocation of the participant to the specific group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This randomized, double-blind randomized clinical trial is

a multi-centered patient with a positive control group and will be performed in four groups of patients with musculoskeletal disorders by four physicians and physicians in four different health centers. All patients will be given enough information about the properties of ozone and corticosteroid injections, possible side effects, method and duration of testing, and the likelihood of having a candidate from one of the two treatments. All patients will be asked to sign a written informed consent form. In order to blind the patient, the doctor will prepare the injection material in the syringe, and will cover the syringes with an aluminum sheet to avoid being aware of the type of injection. It should be noted that dilution of corticosteroid and normal saline will be done to equalize the volume of all three injectable solutions. Patients in each group will be evaluated by a physical medicine and rehabilitation specialist who is not aware of the type of injection, before the injection, one week after the injection and two months after the injection, and the rate of change between the two groups will be compared at different times. It should be noted that in each center all injections are performed by a constant person (a physical medicine and rehabilitation specialist). Using three-blind coded questionnaires, where the first blind represents the group, the second blind indicates the time of the measurement of the outcome and the third blind represents the patient's code, the analyst will also be unaware of the allocation of people to the treatment groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

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Approval date

2017-07-08, 1396/04/17

Ethics committee reference number

IR.IUMS.REC.1396.30324

Health conditions studied

1

Description of health condition studied

carpal tunnel syndrome

ICD-10 code

G59

ICD-10 code description

Mononeuropathy in diseases classified elsewhere

Primary outcomes

1

Description

Pain score based on Visual Analogue Scale

Timepoint

Before injection, 2 weeks and 8 weeks after injection

Method of measurement

Visual Analogue Scale

2

Description

The functional limitations and symptoms severity scales on Boston Questionnaire

Timepoint

Before injection, 2 weeks and 8 weeks after injection

Method of measurement

Boston Questionnaire

Secondary outcomes

1

Description

Clinical Global Impression

Timepoint

Before injection, 1 weeks and 8 weeks after injection

Method of measurement

Clinical Global Impression Questionnaire

2

Description

Patient Global Impression of Improvement

Timepoint

Before injection, 1 weeks and 8 weeks after injection

Method of measurement

Patient Global Impression of Improvement Questionnaire

3

Description

Electromyographic findings

Timepoint

Before injection, 1 weeks and 8 weeks after injection

Method of measurement

Nerve strip

4

Description

Median nerve cross section

Timepoint

Before injection, 1 weeks and 8 weeks after injection

Method of measurement

sonography

5

Description

Channel depth

Timepoint

Before injection, 1 weeks and 8 weeks after injection

Method of measurement

sonography

6

Description

Flexor Retinaculum Thickness

Timepoint

Before injection, 1 weeks and 8 weeks after injection

Method of measurement

sonography

Intervention groups

1

Description

Intervention group: 2cc ozone 20µg / L, around the median nerve with Medial approach as in-plane under ultrasound guidance.

Category

Treatment - Drugs

2

Description

Control group (corticosteroid therapy): 1cc triamcinolone 40mg + 1cc normal saline, around the median nerve with Medial approach as in-plane under ultrasound guidance.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Medical Research and Training
Hospital, Tabriz University of Medical Sciences

Full name of responsible person

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

70

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

2

Sponsor

Name of organization / entity

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Grant name

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

30

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
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available