Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison Between the Effects of Intramuscular Injection of Ozone and Lidocain on Pain, Range of Motion and Functional Score of Patients with Myofascial Pain Syndrome

Protocol summary

Summary

Objectives: Comparison between ozone and lidocaine intramuscular injection in symptom improving of patients with myofascial pain syndrome (MPS) Design: A double blinded randomized clinical trial on MPS patients referred to physical medicine and rehabilitation (PMR) clinic Setting and conduct: In this study conducted in 2015, patients referred to Shahid Modarres Hospital clinic with suspension of MPS were consecutively recruited. Participants including major eligibility criteria: Among all patients referring to our clinic 62 subjects with confirmed diagnosis of MPS were included. Intervention: Patients randomly categorized into three groups of dry needling (DN), Lidocaine injection (WN: Wet Needling) and ozone injection (OI). Main outcome measures: visual analogue scale (VAS), point pressure threshold (PPT), ROM of the neck and function of the patient were evaluated before and one month after the treatment. Keywords: Myofascial pain syndrome, trigger point, dry needling, wet needling, ozone injection

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042113442N10**
Registration date: **2016-09-01, 1395/06/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-09-01, 1395/06/11

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Between the Effects of Intramuscular Injection of Ozone and Lidocain on Pain, Range of Motion and Functional Score of Patients with Myofascial Pain Syndrome

Public title

The Effects of Intramuscular Ozone Injection in Patients with Myofascial Pain Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 25-60 years old؛ Presence of active trigger points in the upper trapezius muscles؛ Unilateral pain؛ More than 3 months pain Exclusion Criteria:

Cognitive disorders: History of radiculopathy, trauma or previous surgery in neck: Previous treatment of trigger points with needling during last 6 months: Past medical history of fibromyalgia, RA, hypothyroidism and DM

Age
From **25 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Beheshti Univeraity of Medical Sciences, Medical Ethics Committee

Street address
Shahid Beheshti Univeraity of Medical Sciences, Velenjak St, Tehran

City
Tehran

Postal code

Approval date
2016-01-31, 1394/11/11

Ethics committee reference number
IR.SBMU.SM.REC.1394.168

Health conditions studied

1

Description of health condition studied
Myofascial Pain Syndrome

ICD-10 code
M79.1

ICD-10 code description
Myalgia (excl. myositis)

Primary outcomes

1

Description
Pain

Timepoint
0- 4 weeks

Method of measurement
visual analogue scale (VAS), point pressure threshold (PPT)

2

Description
Range of Motion

Timepoint
0- 4 weeks

Method of measurement
Goniometer

Secondary outcomes

1

Description
Functional Score

Timepoint
0-4 weeks

Method of measurement
Neck Disability Index (NDI) questionnaire

Intervention groups

1

Description
Ozone Injection In Trigger Points

Category
Treatment - Drugs

2

Description
Wet Needling (Lidocaine)

Category
Treatment - Drugs

3

Description
Dry Needling (Without Drug)

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Modarres Hospital, Shahid Beheshti Univeraity

of Medical Sciences

Full name of responsible person
Fatemeh Sadeghi

Street address
Shahid Modarres Hospital, Kaj Square, Saadat Abad street, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Vice chancellor for research, Seyed Ahmad Raeissadat

Street address
Physical Medicine and Rehabilitation Departement, Shahid Modarres Hospital, Kaj Square, Saadat Abad, Tehran

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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 Sciences

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
Shahid Beheshti Univeraity of Medical Sciences

Full name of responsible person
Fatemeh Sadeghi

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Assistant in physical medicine and rehabilitation

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Associate Professor

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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