

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

+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

2016-02-20, 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

street, Tehran

City

Tehran

Postal code

Phone

+98 21 2273 1112

Fax

Email

sadeghi_fsv@yahoo.com

Web page address

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

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 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

Position

Assistant in physical medicine and rehabilitation

Other areas of specialty/work

Street address

Shahid Modarres Hospital, Kaj square, Saadat Abad

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti Univeraity of Medical Sciences

Full name of responsible person

Seyed Ahmad Raeissadat

Position

Associate Professor

Other areas of specialty/work

Street address

Shahid Modarres Hospital, Kaj Square, Saadat Abad street, Tahran

City

Tehran

Postal code

Phone

+98 21 2207 4090

Fax

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