

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the Effect of Hyaluronidase and Lidocaine Injection on Myofascial Pain Syndrome

Protocol summary

Study aim

The purpose of this study is to compare the effect of hyaluronidase and lidocaine injection on myofascial pain syndrome.

Design

After obtaining the criteria for entering the study, 26 eligible patients were randomly assigned into three groups of hyaluronidase and lidocaine. After providing explanations for the protocol, pain measurements are based on the VAS scale and neck flexure using a goniometer. The injection method is as follows: 3.2 ml of hyaluronidase (containing 1% hyaluronidase and 0.9% normal saline) and 3.2 ml lidocaine (containing 1% lidocaine and 0.9% normal saline) are injected. Injection is performed on two painful points of trapezius muscle with ultrasound guidance for each patient, and pressure is applied to prevent the bleeding of the injection site for two minutes. It is also used to inject a needle from 25 goggles. The VAS, ROM level is measured before injection, week 1, week 4, week 6 and 12 weeks.

Settings and conduct

Taleghani hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Being in the range of 25 to 75 years
2. Having chronic pain over the past three months
3. Having back pain in the upper area
Exit criteria: 1. Having a history of hypersensitivity to bicarbonate, lidocaine and hyaluronidase
2. Having anticoagulant medication within three days before starting the study
3. Having analgesic drugs, including non-steroidal anti-inflammatory drugs, acetaminophen with drug use five days before the start of the study
4. Having pain associated with trauma six months before the start of the study
5. Having a history of surgery in the shoulder and neck area
6. TPI in the same area three months before the start of the study
7. Having fibromyalgia

Intervention groups

Hyaluronidase injection group And Lidocaine injection group

Main outcome variables

pain rate, Neck flexion rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190304042908N1**

Registration date: **2019-11-01, 1398/08/10**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-01, 1398/08/10**

Update count: **0**

Registration date

2019-11-01, 1398/08/10

Registrant information

Name

mahshid ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Hyaluronidase and Lidocaine Injection on Myofascial Pain Syndrome

Public title

the Effect of Hyaluronidase and Lidocaine Injection on Pain Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient placement in the range of 25 to 75 years Having chronic pain in the last three months Having back pain in the upper area

Exclusion criteria:

Having a history of hypersensitivity to bicarbonate, lidocaine and hyaluronidase Having anticoagulant medication within three days before starting the study Having analgesic drugs, including non-steroidal anti-inflammatory drugs, acetaminophen with drug use five days before the start of the study Having pain associated with trauma six months before the start of the study Having a history of surgery in the shoulder and neck area TPI in the same area three months before the start of the study Having diseases like cancer, endocrinology, depression or schizophrenia. Having obesity (BMI less than 27)

Age

From **25 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients included in the study were divided into 2 groups by a random-number table. The research sample was determined using sampling method based on entry criteria and considering the possibility of destruction, 24 people .People are selected with easy sampling and are enrolled in the study. Then, they are divided into two groups of control and intervention by simple random sampling law

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak

City

tehran

Province

Tehran

Postal code

15683287

Approval date

2019-04-30, 1398/02/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.333

Health conditions studied**1****Description of health condition studied**

Patients who experience chronic pain in the dorsal muscles.

ICD-10 code

G89.4

ICD-10 code description

Chronic pain syndrome

Primary outcomes**1****Description**

Pain rate, Neck muscle flexion

Timepoint

Before injection, week one, week four, week six and week twelve

Method of measurement

Visual Analog Scale VAS Pain: This scale represents the pain of patients in general. This scale is plotted as a 10-cm line, and the pain range is between 0 and 10 cm. The zero number does not show any pain, the number 1 to 3 mild pain, the number 4 to 6 average pain and the number 7 to 10 severe pain. The internal stability of this tool is 0.85. Up to 95 %. ROM: The neck flexion rate is measured using a goniometer. In this way, the goniometer axis is placed in the neck of the neck of the neck and on the proximal shoulder. The fixed arm is held along the horizons and movable arm along the longitudinal line of the neck, and the neck flexion range is asked from the person to move the neck forward without moving the head, and the angular changes are recorded.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Hyaluronidase injection group. Hyaluronidase 3.2 ml (containing 1% hyaluronidase and 0.9% normal saline) are injected. Injection is performed on two painful points of trapezius muscle with ultrasound guidance for each patient and pressure is applied to prevent the bleeding of the injection site for two minutes.

Category

Treatment - Drugs

2

Description

Intervention group 2: Lidocaine injection group. The lidocaine group is injected with 2.3 ml (containing 1% lidocaine and 0.9% normal saline). The injection is performed on two painful points of the trapezius muscle with ultrasound guidance for each patient and is pressed for two minutes to prevent bleeding at the injection site.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Dr. Mahshid Ghasemi

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No.20 , Velenjak St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Ziaee

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Mahshid Ghasemi

Position

assistant profesore

Latest degree

Medical doctor

Other areas of specialty/work

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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

No - There is not 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

No - There is not 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