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
nclusion 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)

Phone
+98 21 2243 2588

Email address
ghasemimahshid529@gmail.com

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
Street address
No.20 , Velenjak St
City
Tehran
Province
Tehran
Postal code
15683287
Phone
+98 21 2243 2588
Email
Ghasemimahshid529@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Seyed Ali Ziaee
Street address
velenjak st
City
tehran
Province
Tehran
Postal code
15683287
Phone
+98 21 2243 2588
Email
mahshidghasemi@sbmu.ac.ir
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
Anesthesiology
Street address
velenjak st
City
tehran
Province
Tehran
Postal code
15683287
Phone
+98 21 2243 2588
Email
mahshidghasemi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr.Mahshid Ghasemi

Position
assistance professor

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
20 velenjak st

City
tehran

Province
Tehran

Postal code
15683287

Phone
+98 21 2243 2588

Email
mahshidghasemi@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mahshid Ghasemi

Position
Assistance professor

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
20 velenjak

City
tehran

Province
Tehran

Postal code
15683287

Phone
+98 21 2243 2588

Email
mahshidghasemi@sbmu.ac.ir

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