Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the pain control effect of liquid phase concentrated growth factors with Lidocaine 2%, masseter and temporalis muscle trigger points and pain free mouth opening in patients with myofascial pain syndrome

Protocol summary

Study aim

This study compares the effectiveness of liquid phase injection of concentrated growth factors (LPCGFs) at trigger points (TrPs) of masseter and temporalis muscles with 2% lidocaine injection at these points on overall pain, trigger point tenderness and painless opening. Oral (PFMO) pays. Patients with pain in muscle trigger points have a low quality of life. Since there is no definitive treatment for this pain, it is necessary to consider the most useful ways to treat it.

Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, phase 3 on 16 patients. It is done by random block method and using excel 2021 software.

Settings and conduct

This research is performed within Shahid Beheshti Dental School. Patients with inclusion criteria are randomly divided into two groups. One group treated with LPCGFs injection and the other group treated with 2% lidocaine injection at study trigger points. VAS is taken from all patients before treatment and 1, 7, 14 and 28 days after treatment session and the results are analyzed.

Participants/Inclusion and exclusion criteria

Patients with myofascial pain syndrome and trigger point in the master or temporalis muscles referred to the Department of Oral and Maxillofacial medicine of Shahid Beheshti Dental School and with inclusion criteria regardless of gender and in the age range of 15 to 80 The year in which the systemic diseases mentioned in the criteria for non-inclusion in the study are not met and they have informed consent.

Intervention groups

The intervention group treated with LPCGFs injection and the control group treated with 2% lidocaine injection were studied at trigger points.

Main outcome variables

Pain intensity of trigger muscle points of the master muscle; Intensity of pain in the trigger points of the temporalis muscle; Severe overall pain; Painless opening of the mouth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220610055126N1**
Registration date: **2022-06-14, 1401/03/24**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-14, 1401/03/24**
Update count: **0**

Registration date

2022-06-14, 1401/03/24

Registrant information

Name

Marzieh Alimohammadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-13, 1401/03/23

Expected recruitment end date

2022-11-14, 1401/08/23

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the pain control effect of liquid phase concentrated growth factors with Lidocaine 2%, masseter and temporalis muscle trigger points and pain free mouth opening in patients with myofascial pain syndrome

Public title
Comparing the effect of liquid phase concentrated growth factors with 2% lidocaine in the management of patients with myofascial pain syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 15 and 80 years [≥15 and ≤80] Presence of at least one trigger point in the masseter or temporalis muscle, previously detected Patient's agreement for participation in this study. Presence of myofascial pain within masseter muscles according to the RDC/TMD (Ia and Ib)
Exclusion criteria:
Patients being treated or addicted to painkillers and / or drugs that affect muscle function. Such as: muscle relaxants, anti-inflammatory, benzodiazepines Patients with mental disorders Patients with neuropathic pain and neurological disorders (trigeminal neuralgia) Patients with headache Edentulous patients Patients after radiotherapy Pregnancy or lactation Pain of dental origin Drug and/or alcohol addiction Patients with needle phobia Patients with bleeding disorders Metabolic (diabetes) and vascular diseases
Age
From **15 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **16**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment of patients to two groups is done using the random block method and using excel 2021 software
Blinding (investigator's opinion)
Single blinded
Blinding description
Adjusting the follow-up time of patients so that they do not meet and talk in the waiting room and are not informed about the nature of the injectable substance in the opposite group (single blind).
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
Faculty of Dentistry, Shahid Beheshti University of Medical Sciences, Shahid Chamran Highway, Evin
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2022-05-24, 1401/03/03
Ethics committee reference number
IR.SBMU.DRC.REC.1401.016

Health conditions studied

1

Description of health condition studied
patients with myofascial pain syndrome
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain intensity of masseter muscle trigger points, pain intensity of temporalis muscle trigger points, general pain intensity, painless opening of mouth
Timepoint
At the beginning of the study (before the start of the intervention) and 7, 14 and 28 days
Method of measurement
Visual Analogue Scale for pain intensity and measurement with a graduated millimeter with an accuracy of one millimeter for maximum mouth opening

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group of patients, we use LPCGF injection to control the pain of trigger points in one session. First we find the muscle trigger points in the master or temporalis muscle (this step is done by a specialist assistant under the supervision of the tutor in the examination room of the Oral and Maxillofacial Diseases Department). To find the trigger points, touch the muscle with medium to high pressure in all its parts. When a trigger point is found in a muscle that is actually like a relatively hard nodule to the touch, it causes a lot of pain in the patient that was determined to be the right touch; Then we disinfect the patient's skin with medical alcohol. Dot the trigger points with disinfected white cosmetic pencil and then take 10 ml of blood from the patient's vein (this step is done by a specialist assistant under the supervision of a competent nurse in the operating room of the gingival surgery ward). And pass into the white cap plastic tubes (Silfradent S.r.l, Sofia, Italy) without anticoagulants and additives (Figure 1). These tubes are centrifuged immediately using a fixed program device (Medifuge CGF; Silfradent S.r.l, Sofia, Italy) (Figure -2) (this step is performed by a specialist assistant under the supervision of a consultant in the operating room of the gingival surgery department. The exact settings of the centrifuge are as follows: 1. Acceleration for 30 seconds, 2-2700 rpm for 2 minutes, 3-2400 rpm for 4 minutes, 4-2700 rpm for 2 minutes, 5 Reduce the speed for 30 seconds and 6-Stop. At the end of the process, 3 parts of centrifuged blood are obtained: (Figure -3) 1. The upper layer contains platelet-poor plasma (PPP), 2- The middle layer They contain a very large and dense LPCGF, and the lower 3-layer contains red blood cells. As the test tubes do not contain anticoagulants, the injection should be given within 5 minutes. Otherwise, the blood clots and turns into a gel and LPCGF cannot be extracted. Therefore, after centrifugation, the middle layer (LPCGF) is removed within 5 minutes. The patient is then placed in the same examination position for injection. We inject the LPCGF produced by a 2ml syringe with a mesotherapy needle with a 30 gauge (AVA TEB, made in Iran). Hold each point of the trigger muscle on the surface of the skin between the thumb and forefinger or middle finger (whichever is more comfortable) and then insert the needle between the fingers perpendicular to the skin surface. The needle is inserted into the muscle until it enters the exact TrP, which is confirmed by the patient's reaction when reaching the trigger point. After the needle is inserted into each TrP, first aspiration is performed and then the LPCGF is slowly injected at a uniform rate for 60 seconds and then the needle is gently removed. Gum surgery is performed). In all patients, lidocaine 2% by 2ml syringe with needle Gage 30 mesotherapy (AVA TEB, made in Iran) is injected into other masticatory muscles if they are painful, so that in the medial trigeminal muscle, the injection site is near the junction of the muscle with the mandibular body and with external access and in the muscle. The lateral trigeminal is the injection site into the lower head of the muscle in the area of the trigomandibular raphe with intraoral access. All patients in both intervention and control groups are advised to take 500 mg of acetaminophen orally in a maximum of two doses every 8 hours if necessary and 8 hours before the first follow-up session. We also recommend instructions and other forms of treatment strategies, such as a softer diet, changing postural habits, and reducing stress and anxiety in life.

Category

Treatment - Drugs

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Description

Control group: In this group, similar to the intervention group, we mark the trigger points of the master and temporalis muscles and mark them with a white cosmetic pencil. Then, 1 ml of 2% lidocaine (5 ml vial) with a 2 ml syringe with mesotherapy needle with 30 gauge (AVA TEB, made in Iran), exactly similar to the injection method in the intervention group, after aspiration, 2% lidocaine into Mark the trigger points slowly, inject at a uniform speed for 60 seconds, and then gently remove the needle. Oral and maxillofacial diseases are performed. All injections are performed by a researcher. In both groups, on the day of injection (immediately before injection), VAS (from zero to 10) of each point is evaluated and averaged. Then, one, seven, fourteen and twenty-eight days after the injection (follow-up sessions), the VAS of each point is evaluated again and their mean is recorded. Follow-up time adjustment of patients is done in such a way that they do not meet and talk in the waiting room and are not informed about the nature of the injected substance in the opposite group (single blind). In all patients, lidocaine 2% by 2ml syringe with needle Gage 30 mesotherapy (AVA TEB, made in Iran) is injected into other masticatory muscles if they are painful, so that in the medial trigeminal muscle, the injection site is near the junction of the muscle with the mandibular body and with external access and in the muscle. The lateral trigeminal is the injection site into the lower head of the muscle in the area of the trigomandibular raphe with intraoral access. All patients in both intervention and control groups are advised to take 500 mg of acetaminophen orally in a maximum of two doses every 8 hours if necessary and 8 hours before the first follow-up session. We also recommend instructions and other forms of treatment strategies, such as a softer diet, changing postural habits, and reducing stress and anxiety in life.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Oral and Maxillofacial Diseases, Shahid Beheshti Dental School

Full name of responsible person
Marzieh Alimohammadi

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Shahid Chamran Highway, Evin, Daneshjoo Blvd., School of Dentistry, Shahid Beheshti University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
researcher(Marzieh Alimohammadi)

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Marzieh Alimohammadi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Oral and maxillofacial medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
In order to conduct a review or meta-analysis.

From where data/document is obtainable
Email, Fax

What processes are involved for a request to access data/document
1 month

Comments