

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation of the effect of botulinum toxin type A injection for reducing the pain in patients with myofascial pain

Protocol summary

Summary

This study has been designed to assess the effect of botulinum toxin A in compare to isotonic normal saline on relieving myofascial pain due to temporomandibular disorder. The inclusion criteria include being diagnosed with myofascial type of temporomandibular disorder and the pain score equal or more than 30 based on visual analogue scale. Exclusion criteria include history of allergic reaction to botulinum toxin A and history of neurologic pains and the pain score being less than 30 based on visual analogue scale. 34 patients who fulfill inclusion and exclusion criteria will enter the study and will be randomly divided into two groups of 17 named intervention and placebo. All patients will receive both botulinum toxin A and placebo in crossover method. Patients in intervention group will receive 150 units of botulinum toxin A (diluted in 1 cc normal saline) which will be injected in several points on masseter and temporalis muscles based on level of tenderness of said points and they will be followed 1 and 4 months after intervention, then at the fifth month after the first injection they will receive 1 cc of normal saline which will be injected in the same sites, then they are again followed at first and fourth months after placebo treatment. The patients in placebo group will receive the same treatment but in reverse order. The main outcome was pain which measured based on visual analogue scale. The secondary outcome is psychosocial status based on McGill and SCL-90R questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051527894N2**

Registration date: **2017-04-26, 1396/02/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-26, 1396/02/06

Registrant information

Name

Mahdis Masoudrad

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3391 6692

Email address

masoudrad.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-06-05, 1396/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of botulinum toxin type A injection for reducing the pain in patients with myofascial pain

Public title

comparison of the effect of botulinum toxin A injection with placebo in reducing the pain of patients with

myofacial pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are: minimum patient's age of 18 years; the disease being diagnosed as myofascial type of temporomandibular disorder; the pain score equal or more than 30 based on visual analogue scale. Exclusion criteria: presence of connective tissue inflammatory diseases such as rheumatoid arthritis; temporomandibular disorder other than myofascial type; neuropathic pain or neurologic disorders; history of allergic reaction to botulinium toxin A; pregnancy;

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Blv.

City

Ahvaz

Postal code

6193673166

Approval date

2016-03-15, 1394/12/25

Ethics committee reference number

IR.AJUMS.REC.1394.717

Health conditions studied

1

Description of health condition studied

temporomandibular disorder

ICD-10 code

K07.6

ICD-10 code description

Temporomandibular joint disorders

Primary outcomes

1

Description

patient's pain

Timepoint

before intervention, one month after intervention, 4 months after intervention

Method of measurement

Measurement based on visual analogue scale

Secondary outcomes

1

Description

Patient's Psychosocial status

Timepoint

Before intervention, 1 month after, 4 months after

Method of measurement

MCGill and SCL-90R questionnaires

Intervention groups

1

Description

Intervention: Patients in intervention group will receive 150 units of botulinium toxin A (diluted in 1 cc normal saline) which will be injected in several points on masseter and temporalis muscles and they will be followed up at the first and fourth months after intervention, then at the fifth month after intervention they receive 1 cc normal saline which will be injected in the same sites, then they are again followed up at the first and fourth months after placebo treatment.

Category

Treatment - Drugs

2

Description

Control: The patients in placebo group firstly will receive 1 cc of normal saline which will be injected in several points on masseter and temporalis muscles, then they are followed up at the first and fourth months after placebo treatment then at the fifth month after receiving normal saline, they will receive 150 units of botulinium toxin A (diluted in 1 cc of normal saline) at the same sites and again are followed up at the first and fourth months after injection.

Category

Treatment - Drugs

Hospital, Azadegan Boulevard, Research Deputy of Imam Khomeini Hospital

Recruitment centers

1

Recruitment center

Name of recruitment center

Maxillofacial Operating Room of Imam Khomeini Hospital

Full name of responsible person

Mahdis Masoudrad

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Behzad Sharif Makhmalzadeh

Street address

Golestan Boulevard

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research of Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mahdis Masoudrad

Position

Resident of oral and maxillofacial surgery

Other areas of specialty/work

Street address

Maxillofacial operating room, Imam Khomeini

City

Ahvaz

Postal code

Phone

+98 61 3221 6504

Fax

Email

mahdis.mr@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mahdis Masoudrad

Position

Resident of oral and maxillofacial surgery

Other areas of specialty/work

Street address

Azadegan Avn.

City

Ahvaz

Postal code

Phone

+98 61 3221 6504

Fax

Email

mahdis.mr@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mahdis Masoudrad

Position

Resident of oral and maxillofacial surgery

Other areas of specialty/work

Street address

Maxillofacial operating room, Imam Khomeini Hospital, Azadegan Boulevard, Research Deputy of Imam Khomeini Hospital

City

Ahvaz

Postal code

6193673166

Phone

+98 61 3221 6504

Fax

Email

Web page address

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