Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 botulinium 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 botulinium 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 botulinium toxin A and placebo in crossover method. 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 massetter 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
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Ahvaz Jundishapur University of Medical Sciences
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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 botulinium 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 comittee 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

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
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Golestan Boulevared
City
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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
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

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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