

# 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

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+98 61 3221 6504

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mahdis.mr@gmail.com

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**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*