

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of Botulinum injection on symptoms reduction in patients with Temporomandibular Disorders

#### Protocol summary

##### Study aim

the effect of botulinum toxin injection on the masticatory muscle pain, joint click and maximum jaw opening in patients with temporomandibular disorders

##### Design

Before after non-randomized non-controlled clinical trial on 61 patients selected through intentional sampling during 2018-2017

##### Settings and conduct

The patients will be selected through census method during 2018-2017 and will undergo Botulinum A toxin injection into the masseter muscle. All patients will be assessed one week, one month, three months and six months after the injection for the before-after difference in the Visual Analysis Scale, joint clicking (during touch) and mouth opening (by measuring the distance between the upper and lower incisors).

##### Participants/Inclusion and exclusion criteria

The diagnosis of patients was based on medical history and increased muscle stiffness including pain triggers; individuals over 18 years old who went under the conservative treatment for 3 months are included; The patients undergoing the surgical procedures or having previous injection of botulinum toxin and heat-treated physiotherapy are excluded.

##### Intervention groups

A total of 50 units of Dysport botulinum toxin will be injected into the masseter muscle of all patients.

##### Main outcome variables

presence or absence of joint click by touch; the amount of pain; mouth opening rate were evaluated by measuring the distance between the upper and lower incisors

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130710013938N4**

Registration date: **2018-04-09, 1397/01/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-04-09, 1397/01/20**

Update count: **0**

##### Registration date

2018-04-09, 1397/01/20

##### Registrant information

###### Name

Mohamadali Ghavimi

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3335 5968

###### Email address

ghavimim@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-28, 1396/12/09

##### Expected recruitment end date

2018-06-02, 1397/03/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Botulinum injection on symptoms reduction in patients with Temporomandibular Disorders

##### Public title

Effect of Botulinium injection on symptoms reduction in patients with Temporomandibular Disorders

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients with temporomandibular disorders whom were under conservative treatment for 3 months

#### Exclusion criteria:

Patients have been undergone surgical procedures or have history of previous injection of botulinum toxin

### Age

From **18 years** old

### Gender

Both

### Phase

2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Single

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Central Building of Tabriz University of Medical Sciences, Daneshgah Street, Tabriz, Iran

##### City

tabriz

##### Province

East Azarbaijan

##### Postal code

5166614711

#### Approval date

2018-02-26, 1396/12/07

#### Ethics committee reference number

IR.TBZMED.REC.1396.1098

## Health conditions studied

### 1

#### Description of health condition studied

Temporomandibular Disorder

#### ICD-10 code

M26.6

#### ICD-10 code description

Temporomandibular joint disorders

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

1 week, 1 month, 3 months and 6 months after injection

#### Method of measurement

Visual Analogue Scale for pain

### 2

#### Description

Temporomandibular joints click sound

#### Timepoint

1 week, 1 month, 3 months and 6 months after injection

#### Method of measurement

palpation

### 3

#### Description

maximum jaw opening

#### Timepoint

1 week, 1 month, 3 months and 6 months after injection

#### Method of measurement

ruler with accuracy up to one millimeter

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients with Temporomandibular Disorder undergo total of 50 units of botulinum Dysport toxin injection at the trigger point in the masseter muscle

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tabriz Faculty of Dentistry

##### Full name of responsible person

Atena Afzali Mehr

**Street address**

Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, IRAN

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**Email**

nfo@dentistryfac.tbzmed.ac.i

**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Ghavimi

**Street address**

Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, IRAN

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Ghavimim@tbzmed.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

#### **Full name of responsible person**

Mohammad Ali Ghavimi

#### **Position**

Associate professor

#### **Latest degree**

Specialist

#### **Other areas of specialty/work**

Maxillofacial surgery

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Ghavimi

**Position**

Associate professor

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

data can be shared anonymously

**When the data will become available and for how long**

Data will be available from 2019

**To whom data/document is available**

academic Researchers

**Under which criteria data/document could be used**

There are no specific conditions

**From where data/document is obtainable**

Faculty of Dentistry, Tabriz University of Medical  
Sciences, Golgasht Ave, Tabriz, IRAN Tel :  
+98-41-33355965-9 Fax : +98-41-33346977

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

6 months

**Comments**