

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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)

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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 Botulinum 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

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

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?

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 updating data

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

6 months

Comments