Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of Botolinium 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 mounts 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 Botolinium injection on symptoms reduction in patients with Temporomandibular Disorders

Public title

Effect of Botolinium 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

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3335 5965

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

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3335 5965

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

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Phone
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Email
Ghavimim@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

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Tabriz University of Medical Sciences

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Mohammad Ali Ghavimi

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Associate professor

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Person responsible for updating data

Contact

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Tabriz University of Medical Sciences

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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