

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Complication and Pain Comparison of 2 Brands of Botulinum Toxin A, Diluted with Lidocaine vs Normal Saline

Protocol summary

Study aim

Main Aim Determining amount of pain and complications due to injection of 2 brands of Botulinom Toxin type A diluted with lidocaine or normal saline of patients in Buali hospital in 1399 Specific Aims

Design

Clinical trail with control group, with parallel groups, double blinded, randomized, phase 3 on 64 patients, Exel's random function used for randomization

Settings and conduct

Research will be done Clinical Trial, Double Blinded method on 64 patients Participants are randomly assigned to three different groups A, B and C In each group there is one sample with a specific code and patients are selected using Exel software's random selection. Coded syringes will be handed to the operator who is a specific person in each group The operator will perform the injection on 20 spots without knowing the injection material, dilution material and related codes and fill out form The questionnaires will be sorted by codes and patients will not know about the injection material Patient will rate their pain according to VAS scale Patient will rate their pair according to VAS scale wherein highest tolerable pain is rated 10 Possible complications which are Ptosis, Asymmetry and Diplopia will be examined in patient next visit after 2 weeks

Participants/Inclusion and exclusion criteria

All participants without Systemic Disease who have expressed their written approval, haven't experienced previous unpleasant injection and are not allergic to Botulinum Toxin

Intervention groups

Group A: patients who received Dysport diluted with Normal Saline Group B: patients who received Dysport diluted with lidocaine Group C: patients who received Xeomin diluted with Normal Saline

Main outcome variables

Pain; Ptosis; Asymmetry; Diplopia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210401050804N1**

Registration date: **2021-04-26, 1400/02/06**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-26, 1400/02/06**

Update count: **0**

Registration date

2021-04-26, 1400/02/06

Registrant information

Name

diba bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2212 1467

Email address

diba.bgi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-25, 1400/02/05

Expected recruitment end date

2021-07-27, 1400/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Complication and Pain Comparison of 2 Brands of Botulinum Toxin A, Diluted with Lidocaine vs Normal Saline		Medical sciences faculty of Dentistry	
Public title		Street address	
Complication and Pain Comparison of 2 Brands of Botulinum Toxin A, Diluted with Lidocaine vs Normal Saline		No. 4, 10th Neyestan Ave., Pasdaran St., Tehran	
Purpose		City	
Prevention		Tehran	
Inclusion/Exclusion criteria		Province	
Inclusion criteria:		Tehran	
All patients without any Systemic disease		Postal code	
Exclusion criteria:		19585/175	
Patients who have experienced unpleasant injection will be eliminated from the study Patients who are allergic to Botulinum Toxin		Approval date	
Age		2021-03-07, 1399/12/17	
No age limit		Ethics committee reference number	
Gender		IR.IAU.DENTAL.REC.1399.301	
Both		Health conditions studied	
Phase		<u>1</u>	
3		Description of health condition studied	
Groups that have been masked		Facial aging	
No information		ICD-10 code	
Sample size		ICD-10 code description	
Target sample size: 96		Primary outcomes	
Randomization (investigator's opinion)		<u>1</u>	
Randomized		Description	
Randomization description		Pain	
Participants are randomly assigned to three different groups A, B and C In each group there is one sample with a specific code and patients are selected using Exel software's random selection (Thus each patient entering the study will be coded and assigned to one the groups A, B and C by Exel)		Timepoint	
Blinding (investigator's opinion)		Pain during injection	
Double blinded		Method of measurement	
Blinding description		Patient will rate their pain according to Visual Analogue Scale wherein highest tolerable pain is rated 10 (0 to 3 means mild pain; 4 to 6 is considered moderate pain; 7 to 10 is severe pain)	
Coded syringes will be handed to the operator who is a specific person in each group The operator will perform the injection without knowing the injection material, dilution material and related codes and fill out form The questionnaires will be sorted by coeds and patients will not know about the injection material		Secondary outcomes	
Placebo		empty	
Not used		Intervention groups	
Assignment		<u>1</u>	
Parallel		Description	
Other design features		Control group: Group A: 100 mg Botulinum Toxin manufactured by Ipsen sold under the trade name Dysport, mixed with 1 ml Normal Saline without preservative	
Secondary Ids		Category	
empty		Prevention	
Ethics committees		<u>2</u>	
<u>1</u>		Description	
Ethics committee		Intervention group No. 1: Group B; 100 mg Botulinum Toxin manufactured by Ipsen sold under the trade name Dysport, mixed with 1 ml Lidocaine 2%	
Name of ethics committee		Category	
Ethics committee of Islamic Azad University Tehran		Prevention	

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Description

Intervention group No. 2: Group C; 100 mg Botulinum Toxin manufactured by Merz sold under the trade name Xeomin, mixed with 1 ml Normal Saline without preservative

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

BooAli hospital

Full name of responsible person

Farzin Sarkarat

Street address

Damavand Ave, Emam Hosein Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

17117

Phone

+98 21 3334 8036

Fax

+98 21 3378 6182

Email

booali.hospital96@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Arash Azizi

Street address

No. 4, 10th Neyestan Ave., Pasdaran St., Tehran

City

Tehran

Province

Tehran

Postal code

19585/175

Phone

+98 21 2256 4571

Email

drarashazizi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Diba Bagheri

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

No. 29, West Bidar St., Kooye Faraz St., Saadat Abad St., Tehran

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Tehran

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be available to share after the participants are unrecognizable

When the data will become available and for how long

Access will be granted 6 months after results get published

To whom data/document is available

University and scientific organization's researchers

Under which criteria data/document could be used

For future research

From where data/document is obtainable

Cranio MaxilloFacial Research Center of Islamic Azad University of Tehran - Dental branch

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

Mailing Cranio MaxilloFacial Research Center of Islamic Azad University of Tehran - Dental branch

Comments