

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Investigating the effect of using botulinum toxin A in emotional movements of the nostrils in patients undergone rhinoplasty.

Protocol summary

Study aim

To determine the effect of using botulinum toxin A to prevent changes caused by emotional movements of the nostrils in patients who have undergone rhinoplasty.

Design

Clinical trial with control group with parallel groups, without blinding, randomized and phase 3 on 60 patients. The table of random numbers will be used for randomization.

Settings and conduct

This clinical trial study will be conducted in 1402 in Al-Zahra Hospital on patients who have had a history of rhinoplasty, and these patients will be injected with 100 units of botulinum toxin around the muscles of the nasal lobes. Blinding was not done in this study.

Participants/Inclusion and exclusion criteria

This study is carried out on the population of patients who had the inclusion conditions including a history of rhinoplasty and informed consent. Exclusion criteria: psychological disease or history of anticoagulant treatment.

Intervention groups

The intervention performed in the intervention group is the injection of 100 units or 2.5 ml of botulinum toxin A manufactured in MASON pharmacological company to the muscles around the nostrils in one session after rhinoplasty surgery, and no injection is performed in the control group.

Main outcome variables

emotional movements of nostrils

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230418057953N1**

Registration date: **2023-05-15, 1402/02/25**

Registration timing: **prospective**

Last update: **2023-05-15, 1402/02/25**

Update count: **0**

Registration date

2023-05-15, 1402/02/25

Registrant information

Name

Fatemeh Mehrabipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3673 4042

Email address

fatemehmehrabipour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of using botulinum toxin A in emotional movements of the nostrils in patients undergone rhinoplasty.

Public title

botulinum toxin A in emotional movements of the nostrils

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

history of rhinoplasty age between 18 and 65 informed consent

Exclusion criteria:
history of psychiatric disorders using anticoagulants
history of same area botox in past 6 months pregnancy and breastfeeding

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To generate random numbers, a table of random numbers was used, and the researcher places his finger on a number and then moves up and to the left. Based on the sample size, a number of envelopes with aluminum wrappers, prepared and each of the randomly generated sequences are written on a card and the cards are placed inside the envelopes in order. To maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the envelopes is glued and placed in a box. Then, according to the order of entry of the participants in the study, an envelope is opened and a random sequence is determined. If the number inside the envelope is odd, the patient will be placed in the first group, and if it is even, the patient will be placed in the second group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of school of medicine of Isfahan
University of Medical Sciences

Street address

Isfahan, Hazar Jarib Street, Isfahan University of
Medical Sciences, Building No. 3, Faculty of Medicine,
Ground Floor, Department of Medical Ethics Contact
number: 03137928105

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2023-04-15, 1402/01/26

Ethics committee reference number

IR.MUI.MED.REC.1402.042

Health conditions studied

1

Description of health condition studied

rhinoplasty

ICD-10 code

Z42.8

ICD-10 code description

Encounter for other plastic and reconstructive surgery
following medical procedure or healed injury

Primary outcomes

1

Description

emotional movements of nostrils

Timepoint

before the botox injection and 1 week and 1 month after
injection

Method of measurement

FACE questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: injection of 100 units equivalent to
2.5 ml of botulinum toxin A manufactured in MASON
pharmacological company into the muscles of the
nostrils in one session after rhinoplasty. This work is
done with the help of a 30 gauge needle in the Depressor
septi nasi and Levator labii superior alaeque nasi
muscles. the botox manufactured in MASON
pharmacological company.

Category

Treatment - Drugs

2

Description

Control group: without injection

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Fateme Mehrabipour

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Hezar Jarib Ave, Isfahan town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

Street address

Hezar Jerib Avenue, Isfahan, Isfahan province, postal code 8174673461

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askari@mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Fatemeh Mehrabipour

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Fatemeh Mehrabipour

Position

resident

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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

no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available