

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison the effect of intradermal injections of botulinum toxin and normal saline in the treatment of enlarged facial pores

Protocol summary

Study aim

Comparison the effect of intradermal injections of botulinum toxin and normal saline in the treatment of enlarged facial pores

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 33 patients, a random number table is used for randomization.

Settings and conduct

This study will be performed from April 1400 to July 1400 in Ahvaz Imam Khomeini Hospital affiliated to Ahvaz University of Medical Sciences. The study includes patients who refer to the dermatology clinic of Imam Khomeini Hospital in Ahvaz for treatment of large facial skin pores and are willing to cooperate and meet the inclusion criteria. Mark 10 points on each side of the species in a distance of 1 cm. Dilute each vial of 500 units of Masport (Masun Daroo-Alborz, Iran) with 10 ml of normal saline and inject 0.05 ml (2.5 units of Masport) intradermally with a 30G insulin syringe (AVA, Iran) in one cheek (Randomly) and in the opposite site, mark 10 points in distance of 1 cm and 0.05 ml of normal saline will inject. The patient and the therapist are blinded and will not know how to assign the type of treatment to the left and right cheeks.

Participants/Inclusion and exclusion criteria

Inclusion condition: People with large facial skin pores
No entry conditions: Pregnant women and breastfeeding mothers
Age under 15 years
Active disease or infection on face skin
Use of laser, retinoids, hydroquinone, microneedling and other methods of large pore treatment
History of Botox allergy
Neurological diseases

Intervention groups

Intradermal injection of Botox and normal saline in the left and right cheeks with random selection for people who complain about large facial skin pores.

Main outcome variables

Reduce the diameter of facial pores, Reduce facial skin oil, reduce facial skin redness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210321050754N1**

Registration date: **2021-04-19, 1400/01/30**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-19, 1400/01/30**

Update count: **0**

Registration date

2021-04-19, 1400/01/30

Registrant information

Name

Saeed Ashoori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3392 2879

Email address

saeed7840@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-07-06, 1400/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of intradermal injections of botulinum toxin and normal saline in the treatment of enlarged facial pores	
Public title	Comparison of the effect of Botox injection in reducing the size of facial pores
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: People with large pores Exclusion criteria: Pregnant women and breastfeeding mothers Active disease or infection on face skin History of Botox allergy Use of laser, retinoids, hydroquinone, microneedling and other methods of large pore treatment Neuromuscular diseases
Age	From 15 years old to 60 years old
Gender	Both
Phase	3
Groups that have been masked	• Participant • Care provider • Investigator
Sample size	Target sample size: 33
Randomization (investigator's opinion)	Randomized
Randomization description	In order to randomize assignment of types of treatment to the left and right of patients' face, we consider two modes of treatment AB (treatment A left and treatment B right) and BA (treatment B left and treatment A right). So that the nature of treatment A and B will be determined by the official who is not involved in the process of treatment and data analysis. By using random numbers from the table of random numbers, whenever an individual number is observed, AB treatment is assigned to the individual and whenever an even number is observed, BA treatment is considered for the patient. If necessary, this process can be continued until the number of AB and BA treatments is the same. In other words, according to the sample size (33 people) whenever the frequency of one of the two methods reaches 17, for the rest of the patients, another method will be considered.
Blinding (investigator's opinion)	Double blinded
Blinding description	The study is a double-blind study. The patient and the therapist will not know how to assign the type of treatment to the left and right cheeks.
Placebo	Used
Assignment	Parallel
Other design features	

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

13th floor, Block A, Treatment and Medical Education, Headquarters of the Ministry of Health, Iran TV St, between South Flamek and Zarafshan, Ghods Town (West), Tehran

City

Tehran

Province

Tehran

Postal code

Approval date

2021-02-09, 1399/11/21

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.173

Health conditions studied

1

Description of health condition studied

Large pores of facial skin

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The size of the pores of the facial skin

Timepoint

Initiation of the study (before the intervention), 2 weeks and 3 months after the start of the study

Method of measurement

Using the Optic Coherence topography device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intradermal injection of botulinum toxin in one of the studied species (random selection)

Category

Treatment - Drugs

2

Description

Control group: Intradermal injection of normal saline in another species (random selection)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital

Full name of responsible person

Saeed Ashoori

Street address

Dermatology clinic, Emam Khomeini Hospital,
Azadegan (24 metri) Ave

City

Ahvaz

Province

Khouzestan

Postal code

6155945813

Phone

+98 61 3392 2879

Email

saeed7840@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi moghadam

Street address

Golestan , Ahvaz Jondishapur University of Medical
Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3373 8383

Email

ahmadi-m@ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Saeed Ashoori

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No. 36, East 7th Street, Kianpars

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Saeed Ashoori

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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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

Not applicable

Title and more details about the data/document

Personal information including age, sex, pore diameter before and after Botox injection and normal saline

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Dermatologists Academic researchers Permitted analyzes: descriptive

From where data/document is obtainable

E.mail : saeed7840@yahoo.com tel : 00989166042796

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

The requested information will be provided to the applicant one month after receiving the email.

Comments