

# 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 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Public title</b>                                                                                                            | Comparison of the effect of Botox injection in reducing the size of facial pores                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Purpose</b>                                                                                                                 | Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Inclusion/Exclusion criteria</b>                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Inclusion criteria:</b>                                                                                                     | People with large pores                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Exclusion criteria:</b>                                                                                                     | Pregnant women and breastfeeding mothers<br>Active disease or infection on face skin<br>History of Botox allergy<br>Use of laser, retinoids, hydroquinone, microneedling and other methods of large pore treatment<br>Neuromuscular diseases                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Age</b>                                                                                                                     | From <b>15 years</b> old to <b>60 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Gender</b>                                                                                                                  | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Phase</b>                                                                                                                   | 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Groups that have been masked</b>                                                                                            | <ul style="list-style-type: none"> <li>• Participant</li> <li>• Care provider</li> <li>• Investigator</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Sample size</b>                                                                                                             | Target sample size: <b>33</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Randomization (investigator's opinion)</b>                                                                                  | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Randomization description</b>                                                                                               | 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. |
| <b>Blinding (investigator's opinion)</b>                                                                                       | Double blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Blinding description</b>                                                                                                    | 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Placebo</b>                                                                                                                 | Used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Assignment</b>                                                                                                              | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Other design features</b>                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

## 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

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6155945813

##### Phone

+98 61 3392 2879

##### Email

saeed7840@yahoo.com

## 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

Dermatology

##### Street address

No. 36, East 7th Street, Kianpars

##### City

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##### Province

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##### Postal code

6155945813

##### Phone

+98 61 3392 2879

##### Email

saeed7840@yahoo.com

## Person responsible for updating data

### 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

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6155945813

**Phone**

+98 61 3392 2879

**Email**

saeed7840@yahoo.com

## 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**