Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of Efficacy of Botulinum Toxin In The Treatment Of Acne Vulgaris: A Double-Blind Clinical Trial

Protocol summary

Study aim
The effectiveness of botulinum toxin in the treatment of acne vulgaris

Design
Clinical trial with a control group, double-blind, randomized, phase 3 on 30 patients. Random Allocation software was used for randomization

Settings and conduct
moderate to severe acne are included in this study, botulinum toxin is injected on one side of their face and normal saline is injected on the other side of their face, and the results of the response to the treatment are checked in month two and month four by photography and mexameter scan. Injections are performed in the operating room of Razi Hospital The exact location of the study is Razi Hospital in Tehran

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with moderate to severe acne based on GAGS criteria They are between 18 and 55 years old have the possibility to visit regularly Do not have any contraindications for receiving botulinum toxin Exclusion criteria: having needle phobia Having contraindications to Botox injection Pregnancy and breastfeeding

Intervention groups
Using botulinum toxin on one side of the face and normal saline on the other side of the face

Main outcome variables
The severity of acne on the face

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230529058336N1**
Registration date: **2023-06-12, 1402/03/22**
Registration timing: **prospective**
Last update: **2023-06-12, 1402/03/22**
Update count: **0**

Registration date
2023-06-12, 1402/03/22

Registrant information

Name
Parsa Shiri

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 4441 7432

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parsa.shiri1995@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-25, 1402/04/04

Expected recruitment end date
2025-06-25, 1404/04/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Efficacy of Botulinum Toxin In The Treatment Of Acne Vulgaris: A Double-Blind Clinical Trial

Public title
Efficacy Of Botulinum Toxin In The Treatment Of Acne

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with moderate to severe Acne based on global

acne grading system criteria Age between 18 and 55 years old

Exclusion criteria:

Older than 55 years old Younger than 18 years old Having a contraindication to receiving Botox Having needle phobia Pregnancy and breastfeeding

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to the group of botox injection on one side of the face and normal saline injection on the opposite side of the face through a double-blind block randomization method. So that each person was considered as a block. Double blocks are made in such a way that AB combination is injected into the right side of the person's face with Botox and normal saline is injected into the left side of the face. To prepare a random list from the table of random numbers to this It is used that a random number is selected at each step. If the selected number is between 0 and 4, AB combination is considered and if the selected number is 5 to 9, BA combination is considered.Therefore, we repeat this process many times until qualified patients enter the study. According to the output related to Random Allocation Software which is reported as below, the meaning of code 0001:AB That is, botox is injected into the right side of the first person's face and normal saline is injected into the left side of the first person's face. In addition, code 0002:BA means normal saline will be injected on the right side of the second person's face and Botox will be injected on the left side of the second person's face. 0001: BA 0002: AB 0003: AB 0004: BA 0005: AB 0006: BA 0007: AB 0008: BA 0009: AB 0010: BA 0011: AB 0012: BA 0013: AB 0014: BA 0015: BA 0016: AB 0017: BA 0018: AB 0019: BA 0020: AB 0021: AB 0022: BA 0023: BA 0024: AB 0025: AB 0026: BA 0027: BA 0028: AB 0029: AB 0030: BA

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient does not know on which side of the face we want to inject Botox or normal saline. Coding is done by one of the colleagues of the project, and the evaluator and the patient are blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Vahdat Eslami Street, Razi Hospital

City

Tehran

Province

Tehran

Postal code

1199663910

Approval date

2023-05-31, 1402/03/10

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.127

Health conditions studied

1

Description of health condition studied

Acne vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

The number of active papules and pustules and comedones

Timepoint

The effect of botulinum toxin in the treatment of acne vulgaris is investigated in the follow-up of patients at the beginning of the study and at month two and month four.

Method of measurement

Mexameter and photography device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients with moderate to severe

acne based on the GAGS criteria, which are examined in 6 areas in this system: forehead, right cheek, left cheek, nose, chin and upper body. First, each lesion is given a grade based on its severity: no lesion = 0, comedone = 1, papule = 2, pustule = 3, and nodule = 4. The final score for each location (Local Score) is calculated as follows.Factor × grade, in the end, the global score will be the sum of the local scores. A score of 1 to 18 is mild acne, 19 to 30 is moderate acne, 31 to 38 is severe acne, and more than 39 is very severe acne.Patients' faces are divided into right and left face groups by double-blind randomization method. On the control side, 20 points are selected in one half of the face and a volume of one cc or precisely 0.2 cc of placebo is injected in each point, which is the same as normal saline (12 cheek points, 6 forehead areas and two chin areas are selected)) and 20 points are selected on their intervention side (the number of areas and their locations are the same as the intervention side) and 20 units of botulinum toxin (Dystone company brand) and 0.2 cc are injected in each point. The injection is done only once. Both sides of the patient's face will be treated with topical clindamycin 2%, which is manufactured by Razi Hospital Pharmacy.Patients are evaluated by the evaluator at the beginning of the visit and at the second and fourth month

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasi Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
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Position
Resident
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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
The individual information of the disease was confidential and the report was general about the effect of the treatment on all suicide patients Community Verified icon

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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available