

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Study of efficacy, satisfaction and safety of standard treatment plus intradermal injection of microbotox versus standard treatment lonely in the treatment of Androgenetic Alopecia (AGA): A single blind controlled randomized clinical trial

Protocol summary

Study aim

Study of efficacy, satisfaction and safety of standard treatment plus intradermal injection of microbotox versus standard treatment lonely in the treatment of Androgenetic Alopecia

Design

randomized, single-blinded, parallel-group, controlled clinical trial involving 20 patients. Randomization will be performed by drawing lots using cards containing codes A (control) and B (intervention)

Settings and conduct

Patients with AGA attending the Hazrat Fatemeh Hospital who meet the after providing written informed consent and randomly allocated by lottery to two groups. Control: Topical minoxidil 5% solution once daily for 6 months. Intervention: Topical minoxidil 5% solution once daily for 6 months plus intradermal microbotox injection. Dermoscopic and VisioFace assessments will be evaluated by a blinded dermatologist.

Participants/Inclusion and exclusion criteria

Inclusion Criteria - Male patients diagnosed with androgenetic alopecia. - Patient compliance with the therapeutic interventions - No treatment for androgenetic alopecia during the preceding 3 months. Exclusion Criteria - Presence of liver disease. - History of hypersensitivity to any of the therapeutic modalities. - Use of medications that may interact with the therapeutic modalities

Intervention groups

Control Group Participants in the control group will receive topical minoxidil 5% solution applied to the scalp once daily for 6 months as the standard treatment for androgenetic alopecia. Intervention Group Participants in the intervention group will receive topical minoxidil 5% solution applied to the scalp once daily for 6 months as the standard treatment for androgenetic alopecia, in

addition to intradermal microbotox injections administered once monthly for a total of three sessions.

Main outcome variables

Treatment efficacy assessed by trichoscopy and VisioFace imaging

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260624069936N1**

Registration date: **2026-09-09, 1405/06/18**

Registration timing: **registered_while_recruiting**

Last update: **2026-09-09, 1405/06/18**

Update count: **0**

Registration date

2026-09-09, 1405/06/18

Registrant information

Name

Mohadeseh Shokrollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 930 821 9491

Email address

m100124sh@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2026-09-23, 1405/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of efficacy, satisfaction and safety of standard treatment plus intradermal injection of microbotox versus standard treatment lonely in the treatment of Androgenetic Alopecia (AGA): A single blind controlled randomized clinical trial

Public title

Study of standard treatment plus intradermal injection of microbotox versus standard treatment lonely in the treatment of Androgenetic Alopecia (AGA)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male patients with androgenetic alopeciaPatient compliance with the prescribed therapeutic interventions and attendance at all treatment sessions and follow-up visits No uptake treatment for at least three months prior to enrollment

Exclusion criteria:

Presence of liver disease History of allergy to any of the treatment modalities Patients receiving medications that may interact with the treatment modalities

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Patients will be evaluated at 1 and 3 months after completion of the study by a blinded dermatologist. The degree of treatment response in both groups will be assessed by a blinded dermatologist.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

Skin Clinic, Fatemeh Hospital, 23rd Street, Asadabadi Street, Yousef Abad, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1433933111

Approval date

2025-06-24, 1404/04/03

Ethics committee reference number

IR.IUMS.FMD.REC.1404.168

Health conditions studied**1****Description of health condition studied**

Androgenetic Alopecia

ICD-10 code

XII

ICD-10 code description

Diseases of the skin and subcutaneous tissue

Primary outcomes**1****Description**

Hair dermoscopic findings include:- Hair density- Vellus hairs- Yellow dots- Perifollicular signs- Hair shaft density- Hair shaft diameter variability

Timepoint

At baseline and at 1 and 3 months after completion of treatment

Method of measurement

Dermatoscop

2**Description**

Improvement in the overall appearance of the hair, as assessed by Visioface imaging obtained from multiple views

Timepoint

At baseline and at 1 and 3 months after completion of treatment

Method of measurement

Assessment of VisioFace images for macroscopic

improvement in hair appearance from multiple views, including the frontal view (hairline), three-quarter views, vertex, and occipital view

Secondary outcomes

1

Description

Patient satisfaction with the improvement achieved following the therapeutic interventions

Timepoint

At baseline and at 1 and 3 months after completion of treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: In this group, in addition to standard treatment with topical minoxidil 5% applied to the scalp once daily for 6 months, an interventional procedure involving intradermal injection of microbotox into the scalp once monthly for a total of three sessions will also be performed. The microbotox solution will be prepared as follows: one 500-unit vial of zibonta (botulinum toxin type A) will be reconstituted with 3 mL of normal saline. Then, 0.5 mL of the resulting solution will be drawn into a 1-mL syringe, followed by the addition of 0.5 mL of normal saline to the syringe. Thus, each 1-mL syringe will contain 100 units of botulinum toxin. Thirty minutes prior to the injection, a topical anesthetic cream will be applied to the intended treatment area. The microbotox will then be injected intradermally into the scalp at injection points spaced 1 cm apart, extending from 1 cm posterior to the hairline to the vertex.

Category

Treatment - Other

2

Description

Control group: For this group, standard treatment for androgenetic alopecia will consist of topical minoxidil 5% solution applied to the scalp once daily for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Fatemeh Hospital, Yousef Abad

Full name of responsible person

Mohadeseh Shokrollahi

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Hazrat Fatemeh Hospital,,Asadabadi Street , 23rd

Street, Yousef Abad, Tehran, Iran

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m100124sh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Majid safa

Street address

Iran University Of Medical Sciences, Hemmat Expressway, Adjacent To Milad Tower,Tehran

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Phone

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Email

info@iums.ac.ir

Web page address

https://iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mohadeseh Shokrollahi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Doctor Tahereh Rahimi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mohadeseh Shokrollahi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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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 may be shared after de-identification of the participants

When the data will become available and for how long

شروع دوره دسترسی 6 ماه پس از چاپ نتایج

To whom data/document is available

The study data and documentation will be made available to individuals at academic and scientific institutions, as well as to employees of pharmaceutical companies.

Under which criteria data/document could be used

Access to the study data and documentation will be permitted after removal of identifying information and de-identification of the participants, solely for scientific and educational research purposes. The data must be used within the scope of scientific and research objectives, and any commercial use, re-identification of participants, or disclosure of identifiable information will be prohibited. Requests for access must include the research purpose, type of data required, proposed analytical methods, and the intended use and data storage procedures. Requests will be reviewed and approved by the principal investigator and/or the relevant university authorities in accordance with

applicable regulations. Statistical and research analyses related to scientific objectives will be permitted, provided that confidentiality is maintained and the participants cannot be identified.

From where data/document is obtainable

Applicants seeking access to the study data or documentation may submit a written request via email to the principal investigator. The request should include the applicant's name and contact information, institutional affiliation, purpose of the request, type of data or documentation required, and intended use of the requested materials. Requests will be reviewed and responded to by the principal investigator and, if necessary, by the relevant university authorities, in accordance with applicable regulations. Contact information: Principal Investigator: Dr. Mohaddeseh

Shokrallahi Email: M100124sh@gmail.com

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

Applicants should submit their requests via email to the principal investigator. Each request will be reviewed with regard to the research purpose, type of data requested, and intended use of the data. Upon approval of the request and confirmation that the eligibility requirements have been met, the requested data and documentation will be provided in a de-identified and non-identifiable format. The review and preparation of the requested data will generally be completed within a maximum of 30 business days from receipt of a complete request. If review by the relevant university authorities is required, the response time may depend on the duration of the review process by the respective authorities

Comments