Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 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)

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+98 930 821 9491

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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
Street address
Hazrat Fatemeh Hospital,,Asadabadi Street ، 23rd Street, Yousef Abad, Tehran, Iran
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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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Province
Tehran
Postal code
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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

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Doctor Tahereh Rahimi
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Other areas of specialty/work
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Person responsible for updating data

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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