

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluating the efficacy of Erbium:YAG laser in Smooth mode with Fotona device combined with topical minoxidil versus topical minoxidil alone on improvement of androgenetic alopecia

Protocol summary

Study aim

To evaluate and compare the efficacy of Erbium:YAG laser (Fotona, Smooth mode) plus topical 5% minoxidil versus topical 5% minoxidil alone on androgenetic alopecia (hair follicle count, severity, satisfaction) in patients at Razi Hospital.

Design

Randomized, evaluator-blinded, parallel-group clinical trial with two arms, using simple random allocation at a 1:1 ratio.

Settings and conduct

Conducted at Razi Hospital dermatology clinic, Tehran. Eligible patients give written consent and are randomized (Random Allocation Software) 1:1. Baseline visit records demographics, disease duration, severity, and dermoscopic imaging. Intervention group undergoes 6 laser sessions (2-week intervals) with adverse-event monitoring; control group applies minoxidil for 4 months. At 4 months, dermoscopic imaging is repeated under identical conditions; a blinded evaluator assesses response, and patients complete a satisfaction questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion: age 18–55; confirmed diagnosis of androgenetic alopecia; Hamilton-Norwood grade 2–5 (men) or Ludwig grade I–III (women); no other anti-hair-loss treatment in past 6 months; written informed consent. Exclusion: scarring alopecia; pregnancy/breastfeeding; systemic diseases affecting hair loss; use of finasteride, dutasteride, or systemic corticosteroids in past 6 months; minoxidil hypersensitivity; poor compliance/follow-up.

Intervention groups

Intervention group: Erbium:YAG laser, Smooth mode (2940 nm, P30 handpiece, fluence 8.5 J/cm², frequency 2 Hz, spot size 7 mm), 6 sessions at 2-week intervals, combined with topical 5% minoxidil twice daily. Control

group: Topical 5% minoxidil twice daily for 4 months, without laser.

Main outcome variables

Hair follicle count in a standardized 2.5 cm² vertex area via dermoscopy (baseline vs. 4 months); patient satisfaction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260522069491N2**

Registration date: **2026-07-18, 1405/04/27**

Registration timing: **prospective**

Last update: **2026-07-18, 1405/04/27**

Update count: **0**

Registration date

2026-07-18, 1405/04/27

Registrant information

Name

Aysa Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2026-11-22, 1405/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the efficacy of Erbium:YAG laser in Smooth mode with Fotona device combined with topical minoxidil versus topical minoxidil alone on improvement of androgenetic alopecia

Public title
Comparison of Fotona Laser Combined with Topical Minoxidil versus Topical Minoxidil Alone for the Treatment of Androgenetic Alopecia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Clinical diagnosis of androgenetic alopecia (AGA) by a dermatologist Hamilton-Norwood stage II-V in men or Ludwig stage I-III in women No use of other anti-hair loss treatments within the previous 6 months Age 18-55 years Written informed consent
Exclusion criteria:
History of scarring alopecia Pregnancy or breastfeeding Systemic diseases affecting hair loss (hypothyroidism, severe iron deficiency) Use of medications affecting hair growth (e.g., finasteride, dutasteride, or systemic corticosteroids) within the previous 6 months Known hypersensitivity to minoxidil Poor compliance or failure to attend scheduled follow-up visits

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

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
This study is a randomized, double-blind, parallel-group clinical trial. Following the initial assessment and confirmation of eligibility based on the inclusion and exclusion criteria, participants will be randomly allocated to one of two treatment groups using a computer-generated randomization sequence (Random Allocation Software). Participants will be assigned to the intervention and control groups in a 1:1 ratio, with 25 participants in each group. The list assigns each patient a sequential number paired with a code (1 or 2) representing one of the two study groups. The principal

investigator is blinded to the meaning of these codes.

Blinding (investigator's opinion)
Double blinded

Blinding description
Based on the patient numbers on the list and the code (1 or 2) recorded in each row, sealed, opaque envelopes are prepared, each labeled on the outside only with the number 1 or 2, while the type of intervention (laser combined with minoxidil, or minoxidil alone) is written inside. These envelopes are given to the treatment-prescribing physician, while the principal investigator remains unaware of the meaning of these codes (i.e., which code represents which intervention). After obtaining the patient's informed consent to participate in the study, the prescribing physician opens the corresponding envelope and administers the assigned intervention (laser or minoxidil) to the patient based on its contents. For dermoscopic imaging, the person performing the dermoscopy is unaware of the patient's assigned group and the type of treatment administered, and only records and reports the images/hair-count results. The dermoscopy results are then forwarded to the statistical analyst, who is likewise unaware of how patients were allocated to each of the two study groups and analyzes the data based solely on the numerical codes (1 or 2). Accordingly, blinding in this study is maintained at three levels: 1. The principal investigator (regarding the meaning of the allocation codes) 2. The person performing dermoscopy/outcome assessor (regarding the patient's treatment group) 3. The statistical analyst (regarding the meaning of the group codes) The only individual aware of the type of intervention is the prescribing physician, who is responsible for administering the intervention based on the envelope's contents; due to the nature of the intervention (the patient's physical presence for laser sessions), blinding of this individual, as well as of the patient, is not feasible.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Medicine- Tehran University of Medical Sciences
Street address
Rooms 604-605, 6th Floor, Central Administration Building, Tehran University of Medical Sciences, Corner of Keshavarz Boulevard and Qods Street, Tehran, Iran.
City

Tehran
Province
Tehran
Postal code
141765383761
Approval date
2026-02-08, 1404/11/19
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1404.728

Health conditions studied

1

Description of health condition studied

Androgenic alopecia

ICD-10 code

L64

ICD-10 code description

Androgenic alopecia

Primary outcomes

1

Description

Hair count

Timepoint

Before treatment and after completion of the treatment course (fourth month)

Method of measurement

Dermoscopic image assessment with hair counting performed by the principal investigator

Secondary outcomes

1

Description

Patient Satisfaction

Timepoint

After completion of treatment

Method of measurement

Patient-reported satisfaction assessed using a three-level scale (low, moderate, high)

Intervention groups

1

Description

Intervention group: Participants in the intervention group (25 patients) will receive Er:YAG laser therapy (Fotona, 2940 nm) using a P30 handpiece with the following parameters: spot size: 7 mm, fluence: 8.5 J/cm², and frequency: 2 Hz. Participants will undergo six treatment sessions at 2-week intervals. At each treatment session, a scalp examination will be performed, and any treatment-related adverse events will be assessed and recorded. Participants in the control group will receive topical minoxidil, applied twice daily for 4 months to the

affected areas of the scalp. For hair count assessment, a 2.25 cm² area in the vertex scalp will be selected as the target assessment site. The exact location of this area will be determined and documented using fixed anatomical landmarks, including the glabella, occiput, and auricle. The selected area will then be divided into four quadrants, and standardized dermoscopic images will be obtained from each quadrant. Four months after treatment initiation (Visit 3), dermoscopic imaging of the same target area will be repeated under identical conditions, including the same lighting, imaging angle, and magnification. Hair follicle counts before and after treatment will be recorded and compared. Finally, a blinded physician assessor will evaluate the clinical improvement, and participants will complete a treatment evaluation and satisfaction questionnaire.

Category

Treatment - Devices

2

Description

Control group: 25 participants will be allocated to the control group and will apply 5% topical minoxidil solution twice daily to the affected areas of the scalp for 4 months. Four months after treatment initiation (Visit 3), dermoscopic imaging of the same predefined target area will be repeated under identical conditions, including the same lighting, imaging angle, and magnification. Hair follicle counts before and after treatment will be determined and recorded. Finally, a blinded physician assessor will evaluate and score the degree of clinical improvement, and participants will complete a treatment evaluation and patient satisfaction questionnaire.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

dr. Zeinab Aryanian

Street address

Razi Dermatology Hospital, Razi Alley, Vahdat-e Eslami Square, Vahdat-e Eslami Street, Tehran, Iran.

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razihospital@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ms. Tahereh Hemmati

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School of Medicine, Tehran University of Medical Sciences, Pour Sina Street, Qods Street, Enghelab Avenue, Tehran, Iran.

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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**

Tehran University of Medical Sciences

Full name of responsible person

dr. Zeinab Arianian

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Razi Dermatology Hospital, Razi Alley, Vahdat-e Eslami Square, Vahdat-e Eslami Street, Tehran, Iran.

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

dr. Zeinab Aryanian

Position

Associate Professor

Latest degree

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Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

Aysa Rezaei

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

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Fax**Email**

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

No additional information is available

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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available