Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 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

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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.

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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

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Sponsors / Funding sources

1

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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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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