

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the efficacy of combination erbium laser and topical minoxidil treatment with topical minoxidil alone in patients with moderate to severe male androgenetic alopecia

Protocol summary

Study aim

The effect of erbium laser in the treatment of androgenetic alopecia

Design

Clinical trial with control group, parallel, quasi-randomized groups on 30 patients and for randomization couple and single days of referral is used.

Settings and conduct

The study is carried out on patients with moderate to severe androgenetic alopecia referred to medical centers of Isfahan University of Medical Sciences. After examination, history and satisfaction of patients who meet the inclusion criteria will be randomly assigned to two groups. The control group receives 5% topical minoxidil solution twice a day and the intervention group, in addition to the mentioned treatment, receives 6 sessions of erbium laser at two-week intervals and after 12 weeks, patients will be compared and evaluated by standard photography and trichogram at the beginning and end of treatment.

Participants/Inclusion and exclusion criteria

Patients with moderate to severe androgenic alopecia who do not have serious systemic diseases, psoriasis and lichen planus, as well as no history of hair transplantation and photosensitivity.

Intervention groups

The control group receives topical minoxidil and in the intervention group, in addition to the mentioned treatment, erbium laser is also performed.

Main outcome variables

Hair thickness, number of hair, change of photographic score, patient satisfaction.

General information

Reason for update

Due to the reluctance of most patients to use finasteride

and considering that minoxidil alone is also a standard and approved treatment, finasteride was excluded from the study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210404050847N1**

Registration date: **2021-04-16, 1400/01/27**

Registration timing: **prospective**

Last update: **2022-11-23, 1401/09/02**

Update count: **1**

Registration date

2021-04-16, 1400/01/27

Registrant information

Name

Zahra Zavareh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3670 2116

Email address

z.zavare@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of combination erbium laser and topical minoxidil treatment with topical minoxidil alone in patients with moderate to severe male androgenetic alopecia

Public title

Effect of Erbium Laser on Androgenetic Alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with androgenetic alopecia in moderate to severe stages Age over 20 years

Exclusion criteria:

Patients with other types of alopecia Patients with psoriasis or lichen planus Any serious systemic disease Patients who are photosensitive Patients who have performed hair transplants in the past.

Age

From **20 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Referring in couple date ,placed in intervention group and referring in single date, placed in control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezarjarib St., Isfahan University of Medical Sciences

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-03-20, 1399/12/30

Ethics committee reference number

IR.MUI.MED.REC.1399.1191

Health conditions studied

1

Description of health condition studied

Androgenetic alopecia

ICD-10 code

L64

ICD-10 code description

Androgenic alopecia

Primary outcomes

1

Description

Increase hair density and thickness.

Timepoint

At the beginning of the study and then 12 weeks later, which is the end of the study.

Method of measurement

Trichogram and standard photography

Secondary outcomes

1

Description

Patient satisfaction score, physician satisfaction score.

Timepoint

At the beginning of the study and then 12 weeks later, which is the end of the study.

Method of measurement

A 7-point questionnaire was allocated for patient satisfaction;also, a 7-point questionnaire developed by a physician based on a comparison of standard photographic scores and trichogram comparisons (checking the thickness and number of hairs).

Intervention groups

1

Description

Intervention group: receiving topical minoxidil 5% twice daily and performing erbium laser in 6 sessions with two-week intervals for 12 weeks

Category

Treatment - Other

2

Description

Control group: receiving topical minoxidil 5% twice daily.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Zahra Zavareh

Street address

Soffe Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo javanmard

Street address

No.4 building.,Esfahan University of Medical Sciences.,Hezar Jerib St

City

Esfahan

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8174673461

Phone

+98 31 3668 5149

Email

research@mui.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Zavareh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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 information

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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