

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 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

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8169663363

**Phone**

+98 31 3620 2020

**Email**

z.zavare@yahoo.com

## 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

**Province**

Isfahan

**Postal code**

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

**Street address**

No. 21, 9th Alley, South Farabi St., Sheikh Koleini Blvd.

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z.zavare@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Zahra Zavareh

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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