

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the efficacy of low-level light laser therapy plus minoxidil 5% and minoxidil 5% alone in the treatment of androgenetic alopecia

#### Protocol summary

##### Summary

This double-blind controlled clinical trial will recruit 50 male and female patients (age: 17-45 years old) with androgenetic alopecia (AGA) who visit the dermatology clinics of Alzahra Hospital, Khorshid Hospital, and Sedighe Tahereh Research Center (Isfahan, Iran). Table of random numbers will be used for random allocation of the patients. Both groups will have to apply 20 drops of a minoxidil topical solution 5% on the affected areas twice daily. The intervention group will also receive low level light laser therapy (LLLT) using a laser comb two-three times a week for 24 weeks. Laser sessions will last for 20 minutes and will be held at Arman Laser Clinic. The patients will be included if the AGA diagnosis is confirmed by careful clinical examination, patient history, Ludwig and Hamilton's criteria, and ruling other causes of hair loss out. A demographic questionnaire will be filled out at baseline. Two researchers unaware of grouping will perform phototrichogram tests at baseline and after three, six, nine, and 12 months. Changes in hair density and hair shaft diameter at the affected site, hair regrowth (based on the patient and researcher's opinion), and patient satisfaction will be compared in two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016022726780N1**

Registration date: **2016-05-02, 1395/02/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-02, 1395/02/13

#### Registrant information

##### Name

Samane Mozafarpour

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3628 9559

##### Email address

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#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

#### Expected recruitment start date

2015-12-11, 1394/09/20

#### Expected recruitment end date

2016-03-10, 1394/12/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparing the efficacy of low-level light laser therapy plus minoxidil 5% and minoxidil 5% alone in the treatment of androgenetic alopecia

#### Public title

Comparing the efficacy of low-level light laser therapy plus minoxidil 5% and minoxidil 5% alone in the treatment of androgenetic alopecia

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: consent to participate; absence of

other causes of hair loss; types 1-4 on Fitzpatrick scale; stages 3-6 on Norwood Hamilton Scale (for male pattern baldness); stages 2-3 on the Ludwig Scale for hair loss in women; no history of finasteride, antiandrogens (e.g. cyproterone, spironolactone, ketoconazole, and flutamide), topical estrogen, progesterone, tamoxifen, anabolic steroids, drugs potentially associated with hypertrichosis (e.g. cyclosporine, diazoxide, phenytoin, oral glucocorticoids, lithium, and phenothiazine during the three-month period before the study. Exclusion criteria: using the above-mentioned medicines during the study; lack of adherence to treatment protocol; hair transplant; any medical conditions leading to hair loss (e.g. HIV/AIDS, connective tissue disease, and inflammatory bowel disease); development of endocrinopathies such as PCO, ovarian and adrenal gland tumors, and hypothyroidism.

**Age**

From **17 years** old to **45 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double 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**

Hezar Jarib St.

**City**

Isfahan

**Postal code****Approval date**

2015-12-09, 1394/09/18

**Ethics committee reference number**

IRMUIREC13943912

**Health conditions studied****1****Description of health condition studied**

Androgenetic alopecia

**ICD-10 code**

L-64

**ICD-10 code description**

Androgenic alopecia

**Primary outcomes****1****Description**

Hair density

**Timepoint**

Before the intervention, 3, 6, 9, and 12 months after the intervention

**Method of measurement**

Phototrichogram

**2****Description**

Hair shaft diameter

**Timepoint**

Before the intervention, 3, 6, 9, and 12 months after the intervention

**Method of measurement**

Phototrichogram

**3****Description**

Patient satisfaction

**Timepoint**

3, 6, 9, and 12 months after the intervention

**Method of measurement**

Questionnaire

**4****Description**

Hair regrowth based on patient's opinion

**Timepoint**

3, 6, 9, and 12 months after the intervention

**Method of measurement**

Visual analog scale

**5****Description**

Hair regrowth based on physician's opinion

**Timepoint**

3, 6, 9, and 12 months after the intervention

**Method of measurement**

Digital image and observation

## Secondary outcomes

### 1

**Description**

Headache

**Timepoint**

3, 6, 9, and 12 months after the intervention

**Method of measurement**

Asking patients

### 2

**Description**

Erythema

**Timepoint**

3, 6, 9, and 12 months after the intervention

**Method of measurement**

Asking patients

### 3

**Description**

Itching

**Timepoint**

3, 6, 9, and 12 months after the intervention

**Method of measurement**

Asking patients

### 4

**Description**

Hypopigmentation

**Timepoint**

3, 6, 9, and 12 months after the intervention

**Method of measurement**

Observation and asking patients

### 5

**Description**

Hyperpigmentation

**Timepoint**

3, 6, 9, and 12 months after the intervention

**Method of measurement**

Observation and asking patients

## Intervention groups

### 1

**Description**

Intervention: 20 drops of a minoxidil topical solution 5% on the affected areas twice daily plus 20-minute sessions of low level light laser therapy (LLLT) using a laser comb (LDU 8024PN/8024BN, Germany) two-three times a week for 24 weeks.

**Category**

Treatment - Devices

### 2

**Description**

Control: 20 drops of a minoxidil topical solution 5% (Pak Darou, Iran) on the affected areas twice daily.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Dermatology Clinic, Alzagra Hospital

**Full name of responsible person**

Samane Mozafarpour

**Street address**

Sofeh Blv.

**City**

Isfahan

### 2

**Recruitment center****Name of recruitment center**

Sedighe Tahereh Dermatology and Sexually Transmitted Diseases Research Center

**Full name of responsible person**

Samane Mozafarpour

**Street address**

Khoram St.

**City**

Isfahan

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Vice Chancellor for Research, Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Bahram Nasr Esfahani

**Street address**

Hezar Jarib St.

**City**

Isfahan

**Grant name**

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**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for Research, Isfahan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

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## Person responsible for general inquiries

### Contact

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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)

*empty*

### Study Protocol

*empty*

### Statistical Analysis Plan

*empty*

### Informed Consent Form

*empty*

### Clinical Study Report

*empty*

### Analytic Code

*empty*

### Data Dictionary

*empty*