

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

s_mozafarpour@resident.mui.ac.ir

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

--

Grant code / Reference number

--

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*

+98 31 3663 3061

Fax**Email**

g_faghihi@med.mui.ac.ir

Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Samane Mozafarpour

Position

Resident

Other areas of specialty/work**Street address**

Hezar Jarib St.

City

Isfahan

Postal code**Phone**

+98 31 3620 2020

Fax**Email**

s_mozafarpour@resident.mui.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Skin Diseases and Leishmaniasis Research Center

Full name of responsible person

Dr Gita Faghihi

Position

Professor

Other areas of specialty/work**Street address**

Sofeh Blv.

City

Isfahan

Postal code

8187698191

Phone**Person responsible for updating data****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Samane Mozafarpour

Position

Resident

Other areas of specialty/work**Street address**

Hezar Jarib St.

City

Isfahan

Postal code

8174675731

Phone

+98 31 3792 9001

Fax

+98 31 3668 8597

Email

s_mozafarpour@resident.mui.ac.ir

Web page address**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*