Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Name of organization / entity
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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 patter 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 Committe 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 Mozafarpoor
Street address
Sofeh Blv.
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Isfahan

2

Recruitment center
Name of recruitment center
Sedighe Tahereh Dermatology and Sexually Transmitted Diseases Research Center
Full name of responsible person
Samane Mozafarpoor
Street address
Khoram St.
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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.
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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

Person responsible for general inquiries

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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