A study comparing laser hair removal with and without a facial cream in women with excess facial hair

Submission date	Recruitment status	Prospectively registered
08/07/2025	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
22/07/2025	Completed	Results
Last Edited	Condition category	Individual participant data
10/07/2025	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Facial hair growth in women, known as hirsutism, can be distressing and affect self-confidence. Intense pulse light (IPL) therapy is commonly used to reduce unwanted hair, but some hair often returns. A cream called effornithine may help improve results when used with IPL. This study aims to find out whether combining the cream with IPL is more effective than using IPL alone.

Who can participate?

Women aged 18–70 years with moderate to severe unwanted facial hair and otherwise normal hormone levels

What does the study involve?

Participants were randomly assigned to receive either IPL treatment alone or IPL combined with eflornithine cream. IPL was given once every 4 weeks for 6 sessions. Those in the combination group also applied the cream twice daily. All participants were followed for 6 months, and hair reduction and satisfaction were assessed.

What are the possible benefits and risks of participating?

Participants may benefit from reduced facial hair growth and increased confidence. Risks are minor and may include temporary skin redness or dryness. No serious side effects were observed in the study.

Where is the study run from? Sandeman Provincial Hospital (Pakistan)

When is the study starting and how long is it expected to run for? August 2023 to February 2024

Who is funding the study? Investigator initiated and funded

Who is the main contact?

Dr M Usman Nawaz, muhammed.nawaz@nhs.net

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPSP Registration Number: CPSP/REU/DER-2021-001-1429

Study information

Scientific Title

Combination of intense pulse light and topical eflornithine therapy versus intense pulse light alone in the treatment of idiopathic facial hirsutism: a randomised controlled trial

Acronym

IPL-EFL

Study objectives

To assess whether adding topical effornithine cream to intense pulse light (IPL) sessions provides better hair reduction outcomes than IPL alone in women with idiopathic facial hirsutism.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 01/08/2023, Sandeman Provincial Hospital (Sandeman Provincial Hospital, Quetta, 87300, Pakistan; +92 (0)2138140600; sandeman.hospital@gmail.com), ref: CPSP/REU/DER-2021-001-1429

Study design

Open-label two-arm parallel-group randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Efficacy

Participant information sheet

Not applicable

Health condition(s) or problem(s) studied

Idiopathic facial hirsutism

Interventions

Participants were randomised using computer-generated block randomisation with a block size of 8 and a 1:1 allocation ratio. Allocation concealment was achieved using sequentially numbered opaque sealed envelopes.

Intervention Arm (Group A):

Participants receive six sessions of intense pulse light (IPL) therapy at 4-week intervals using a quartz-filtered xenon lamp platform (640 nm cut-off filter). In addition, they apply topical eflornithine hydrochloride 13.9% cream (Vaniqa™) to the affected facial area twice daily for 24 weeks.

Control Arm (Group B):

Participants receive the same six-session IPL therapy protocol at 4-week intervals, but do not use any additional topical treatment.

Intervention Type

Mixed

Primary outcome measure

Proportion of participants achieving a ≥1-grade reduction on the modified Ferriman–Gallwey (mFG) scale, measured using the validated photographic mFG scale at week 24

Secondary outcome measures

1. Mean percentage reduction in terminal hair count, measured using dermoscopic digital photography analysed by Image-J software at baseline and week 24

- 2. Patient satisfaction scores, measured using a validated 5-point Likert scale at week 24
- 3. Incidence and severity of treatment-related adverse events, measured using the Common Terminology Criteria for Adverse Events (CTCAE v5.0) at each treatment session and final follow-up (week 24)

Overall study start date

01/08/2023

Completion date

05/02/2024

Eligibility

Key inclusion criteria

- 1. Women aged 18–70 years
- 2. Visible terminal facial hair graded moderate or severe on a validated mFG scale
- 3. Willing to use broad-spectrum sunscreen

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Female

Target number of participants

152

Total final enrolment

152

Key exclusion criteria

- 1. Pregnancy or lactation
- 2. Endocrine disorders (e.g., polycystic ovary syndrome [PCOS], thyroid disease)
- 3. Use of hormonal or anti-androgen therapy within 6 months
- 4. History of light-triggered seizures, keloids, or active facial dermatoses
- 5. Fitzpatrick skin type VI
- 6. Prior adverse reaction to effornithine or IPL

Date of first enrolment

05/08/2023

Date of final enrolment

01/12/2023

Locations

Countries of recruitment

Pakistan

Study participating centre Sandeman Provincial Hospital

Quetta Pakistan 87300

Sponsor information

Organisation

Sandeman Provincial Hospital

Sponsor details

Department of Dermatology Quetta Pakistan 87300 +92 (0)2138140600 sandeman.hospital@gmail.com

Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

15/08/2025

Individual participant data (IPD) sharing plan

No — individual participant data will not be made publicly available. The data will be securely stored for internal analysis only and will not be shared with other researchers.

IPD sharing plan summary

Not expected to be made available