

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Safety and efficacy assessment of Alexandrite laser device (model PG100)in axilla hair reduction

Protocol summary

Study aim

Safety and efficacy assessment of Alexandrite laser device (model PG100)in axilla hair reduction

Design

Single group, phase 2, before -after clinical study. sample size is 30. The study is not randomized.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy, 30 healthy volunteers will be selected and enrolled in the study after signing consent form. Before intervention and at the end of 3 and 6 weeks later changing in axillary hair count will be measured. 6 treatment sessions are performed once a month. This study is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women aged 18 to 50 years ,Skin type 1-4 ,Signing the consent form for participation in the study Exclusion criteria: History of using any type of laser hair removal in the treatment area in the last 12 weeks, If the percentage of white hair in the area is more than 5%, Pregnancy or lactating

Intervention groups

6 treatment session using Alex probe of PG100 device once a month

Main outcome variables

The rate of reduction of axilla hairs in both sides

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N15**

Registration date: **2021-11-23, 1400/09/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-23, 1400/09/02**

Update count: **0**

Registration date

2021-11-23, 1400/09/02

Registrant information

Name

Aniseh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

Email address

a_samadi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy assessment of Alexandrite laser device (model PG100)in axilla hair reduction

Public title

Safety and efficacy assessment of Alexandrite laser device in hair reduction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men and women aged 18 to 50 years Skin type 1-4
Signing the consent form for participation in the study

Exclusion criteria:
History of using any type of laser hair removal in the treatment area in the last 12 weeks If the percentage of white hair in the area is more than 5% Pregnancy or lactating

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Research and Technology Dept, 6th floor, Central Organization of the University, Ghods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-04-28, 1400/02/08

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.100

Health conditions studied

1

Description of health condition studied

unwanted hair

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The rate of reduction of axilla hairs in both sides

Timepoint

Before treatment and 3 and 6 months after last treatment.

Method of measurement

Trichoscopy By Fotofinder

Secondary outcomes

1

Description

Comparison of pain level in both sides

Timepoint

Right after each treatment

Method of measurement

Visual analog scale (VAS)

Intervention groups

1

Description

6 treatment sessions using Alexandrite probe of PG100 device on right and left axilla, with fluence of 5 to 12 joules and pulse width of 20 to 40 mii seconds. Treatment sessions take 10 to 15 minutes with 4 weeks interval.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for research and training in skin diseases and leprosy

Full name of responsible person

Aniseh Samadi

Street address

No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 0658

Email

dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Parnian Gostar Parto Sanj

Full name of responsible person

Jalal Jafari

Street address

No 100, aseman bilding, vanak Sq

City

Tehran

Province

Tehran

Postal code

1991945343

Phone

+98 21 8887 3479

Email

parnian.center@chmail.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Parnian Gostar Parto Sanj

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

Manger of clinical study unit

Latest degree

Ph.D.

Other areas of specialty/work

Skin Biometrics

Street address

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8896 0880

Email

aniseh_samadi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooz

Position

Professor of dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 7921

Email

firozali@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Clinical Research

Street address

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 0658

Email

ahmadi.maryam648@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable