

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Safety and effectiveness of Alma plus laser device (diode laser device) to reduce unwanted hair in the legs area.

Protocol summary

Study aim

Safety and effectiveness of Alma plus laser device (diode laser device) to reduce unwanted hair in the legs area.

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 both of legs hair count will be measured. 4 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

4 treatment sessions using Alma plus laser device produced by Sadra Aqua Company on right and left legs with wavelength at 808 nm, pulse width of 2 to 100 milli seconds and fluence of 1 to 50 joules.

Main outcome variables

The rate of reduction of unwanted hairs of right and left legs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150101020514N19**

Registration date: **2023-01-30, 1401/11/10**

Registration timing: **prospective**

Last update: **2023-01-30, 1401/11/10**

Update count: **0**

Registration date

2023-01-30, 1401/11/10

Registrant information

Name

Alireza Firooz

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 8190

Email address

firozali@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2023-07-11, 1402/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and effectiveness of Alma plus laser device (diode laser device) to reduce unwanted hair in the legs area.

Public title

Safety and effectiveness of Alma plus laser device to reduce unwanted hair

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 in research of medical school-
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

2023-01-23, 1401/11/03

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.700

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 legs hairs in both sides

Timepoint

Before the intervention and 3 months after the last
treatment session

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**

Intervention group: 4 treatment sessions using Alma plus
laser device produced by Sadra Aqua Company on right
and left legs with wavelength at 808 nm, pulse width of 2
to 100 milli seconds and fluence of 1 to 50 joules.

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.

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dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sadra Ako Company

Full name of responsible person
Davoud Yousefvand

Street address
Unit 203, No. 19, Giti Blvd, Nelson Mandela (Jordan)

City
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1966684698

Phone
+98 21 2629 1810

Email
sadraako9@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Sadra Ako Company

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
Azin Ayatollahi

Position
Dermatologist

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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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

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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
Dermatology

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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

No - There is not 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