Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of efficacy and safety of axilla hair reduction using ALX handpiece of MeDioStar NeXTPRO and Cynosure devices.

Protocol summary

Summary

The purpose of this clinical study is to compare the efficacy and side effects of axilla hair reduction using ALX handpiece of MeDioStar and Cynosure devices. The subjects are people aged 18-50 and have not the history of any previous laser and regional electrolysis on study areas. The study is conducted on healthy males and females, willing to consent to participate in the study for axilla hair reduction. The sample size is 20 subjects. The intervention includes 4 treatment sessions on right and left axilla regions, using the ALX handpieces of and Cynosure device. Right or left axilla randomly selected to treat with MeDioStar device and the opposite axilla will be treated with Cynosure. Primary outcome is comparison of percentage of reduction of axilla hairs in right and left axilla, using before and after photos. The secondary outcomes are comparison of skin biophysical changes and pain level in both sides.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015010420514N2**
Registration date: **2016-10-30, 1395/08/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-30, 1395/08/09

Registrant information

Name

Alireza Firooz

Name of organization / entity

Tehran University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

National Institute for Medical Research Development (NIMAD)

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-02-22, 1395/12/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of axilla hair reduction using ALX handpiece of MeDioStar NeXTPRO and Cynosure devices.

Public title

Comparison of two different laser devices for axilla hair reduction.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: males or females with age of 18 – 50 years old; skin types II – IV; the subject must be willing to consent to participate in the study. Exclusion criteria: children and pregnant or lactating women; any previous laser; treatment to the study areas; regional electrolysis within 6 months of study entry; history of keloid scarring; hormonal dysfunction; active cutaneous infection within

the treatment area; chronic sun exposure or tanning; photosensitivity; use of medication with androgenic effects; history of skin pigmentation disorders; cancerous and pre-cancerous lesions in the treatment area; haired nevi in the treatment area; tattoos in the area to be treated.

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Right or left axilla randomly selected to treat with MeDioStar device and the opposite axilla will be treated with Cynosure.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Room 105 , 5th floor, Central construction of Tehran University of Medical Sciences, Ghods intersection, Keshavarz blvd.

City
Tehran

Postal code
1417653761

Approval date
2016-07-10, 1395/04/20

Ethics committee reference number
IR.TUMS.VCR.REC.1395.264

Health conditions studied

1

Description of health condition studied
-

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The percentage of reduction of axilla hairs in both sides.

Timepoint
Before treatment and 3, 6 and 12 months after last treatment.

Method of measurement
Using before and after photos.

Secondary outcomes

1

Description
Comparison of skin biophysical changes in both sides.

Timepoint
Before treatment and 3, 6 and 12 months after last treatment.

Method of measurement
Related probes of MPA device, CK electronic, Germany.

2

Description
Comparison of pain level in both sides.

Timepoint
Right after each treatment.

Method of measurement
Visual analog scale (VAS)

Intervention groups

1

Description
Control group: 4 treatment session using Alex probe of Cynosure device.

Category
Treatment - Other

2

Description
Intervention group: 4 treatment session using Alex probe of Mediostar device.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dowlati Skin Clinic

Full name of responsible person

Dr. Aniseh Samadi

Street address

No 40, Daman Afshar street, Valiasr avenue

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Institute for Medical Research Development (NIMAD)

Full name of responsible person

Reza Malekzadeh

Street address

Between Gharib and Eskandari Ave, Azadi Street.

City

Tehran

Grant name

Grant code / Reference number

943717

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

Yes

Title of funding source

National Institute for Medical Research Development (NIMAD)

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

Contact

Name of organization / entity

Center for research and training in skin diseases and leprosy, Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

Medical Doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Center for research and training in skin diseases and leprosy, Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooz

Position

Dermatologist and professor of Tehran Univercity of Medical Sciences.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Aniseh Samadi

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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