

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Effect of different pulse durations on the efficacy of long-pulsed Alexandrite-assisted hair removal,A split-face comparison study

Protocol summary

Study aim

to determine the effect of different pulse durations on the efficacy of long-pulsed Alexandrite-assisted hair removal

Design

A single blind , randomized clinical trial with a split-face design of 50 subjects with blinded outcome assessment ,single center, community-based,randomization is by use of permuted block randomization

Settings and conduct

Patients go to the Razi hospital every 5 weeks and each session undergo a laser beam therapy using 3 and 10 msec pulse duration on each side of face

Participants/Inclusion and exclusion criteria

Inclusion criteria : Age 18 years and above; female patients with bilateral facial hirsutism Exclusion criteria: patients recieved any drug for hirsutism in last 3 months; severe photosensitivity; keloidal or hypersensitivity scar tendency; recent sun exposure ; pregnancy; lactation

Intervention groups

This is going to be a split-face study and for each patient,one half of face will be test and the other half will be the control.In fact half of the face (that will be chosen randomly) will be treated by 10 msec pulse duration and the other half will undergo treatment with 3 msec pulse duration.

Main outcome variables

The percentage of hair regrowth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191228045917N1**

Registration date: **2020-04-17, 1399/01/29**

Registration timing: **prospective**

Last update: **2020-04-17, 1399/01/29**

Update count: **0**

Registration date

2020-04-17, 1399/01/29

Registrant information

Name

Parvaneh Hatami

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 5560 9951

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-06, 1399/03/17

Expected recruitment end date

2020-10-08, 1399/07/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of different pulse durations on the efficacy of long-pulsed Alexandrite-assisted hair removal,A split-face comparison study

Public title

Effect of pulse duration on laser-assisted hair removal

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age 18 and above facial hirsutism with clinical diagnosis by a dermatologist

Exclusion criteria:

in the last 3 months has not received any drug for hirsutism severe photosensitivity keloidal or hypertrophic scar tendency recent sun exposure pregnancy or lactation

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **2**

one side is beamed by 3 msec pulse duration and the other side by 10 msec

Randomization (investigator's opinion)

Randomized

Randomization description

For random allocation of treatment with two different settings (pulse duration : 3 versus 10 msec), at first, face of subject is divided to 2 parts (right and left), then we generate 50 (number of our subjects) random samples with block randomization with considering 2 treatments and 4, 6 and 8 blocks. Finally, we consider one side of face (that is chosen randomly) constant and based on random sequence generated, allocate the treatment with 10 msec pulse duration to that side of face. It is obvious that the other side will undergo treatment with 3 msec pulse duration. For generation of random sequence, we will use an online software with this address:

<https://www.sealedenvelope.com/simple-randomiser/v1/lists>

Blinding (investigator's opinion)

Single blinded

Blinding description

our subjects will not know each side of their faces will be treated with which pulse duration. two dermatologists that evaluate the photographs are also blinded about the allocation of pulse durations. data analysis also will be done blindly

Placebo

Not used

Assignment

Parallel

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

No. 1, Poorsina Ave., Ghods Ave., Enghelab Ave.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-01-12, 1395/10/23

Ethics committee reference number

IR.TUMS.VCR.REC.1395.143

Health conditions studied

1

Description of health condition studied

Hirsutism

ICD-10 code

L68.0

ICD-10 code description

Hirsutism

Primary outcomes

1

Description

The percentage of hair regrowth

Timepoint

at sessions 5, 10, 15 weeks, the percentage of hair regrowth is measured

Method of measurement

by photographic evaluation by 2 other dermatologists

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: using the manufacture-recommended methods and settings, one side of the face of each patient (randomly determined) is treated with a 10 msec pulse duration using an alexandrite laser (Gentlase Pro, Candela, USA). treatment is conducted every 5 weeks for 3 sessions. hair counts and photographs are obtained before treatment and 1 month postoperatively. This laser has a wavelength of 755 nm, a wide range of pulse duration (3 -300 msec), ability to

generate fluence up to 150 J/cm² and different spotsizes (6 to 18 mm).

Category

Treatment - Devices

2

Description

control group: using the manufacture-recommended methods and settings, the other side of the face of each patient is treated with a 3 msec pulse duration using an alexandrite laser (Gentlase Pro. ,Candela, USA).treatment is conducted every 5 weeks for 3 sessions.hair counts and photographs are obtained before treatment and 1 month postoperatively.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Pedram Nourmohamad Pour

Street address

Razi hospital,Wahdat-e-eslami Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zeynab Aryanian

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

all patient information can be shared without naming and identifying them

When the data will become available and for how long

details of the data are immediately available after publishing the results

To whom data/document is available

all researchers and health professionals working in academic,scientific and medical institutions

Under which criteria data/document could be used

the data is only shared for person whose purpose is to improve the therapeutic course of hirsutism.Any type of statistical analysis can be done in order to improve the treatment

From where data/document is obtainable

Tehran university of medical sciences professor Pedram Nourmohamad Pour Dermatologist Razi hospital, Wahdat-e-eslami Ave., Tehran, District 12 Phone number +98 9128240659 e mail : normohamad@razi.tums.ac.ir

What processes are involved for a request to access data/document

information is available immediately after verifying that the applicant,s circumstances are met by the competent authorities

Comments