

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Comparison of the plasma effect with and without alexandrite laser in the treatment of freckles in patients referred to the clinics affiliated with Tehran Medical Sciences Azad University in 2022-2023

Protocol summary

Study aim

Comparison of plasma efficacy with and without alexandrite laser in the treatment of freckles

Design

A single-blind, randomized clinical trial of 60 patients

Settings and conduct

60 patients with bilateral facial freckles with Fitzpatrick skin type 1 to 4 are treated. A group of 30 patients are treated with single pass plasma and another group of 30 patients are treated with plasma and Cynosure Alexandrite laser. After the treatment, the patient uses zinc oxide daily and eye erythromycin daily for 5 days, and then uses sunscreen with SPF 50 twice a day until at least one month after the treatment. The patients are examined after one month and if necessary, we perform the mentioned treatments once more and finally the clinical improvement and side effects are evaluated by dermatologist. -Place of performance in clinics affiliated to Azad University, Tehran Medical Branch

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Patients with freckles, Skin type 1 to 4 of the Fitzpatrick scale, People over 16 years old
Exclusion criteria: - Use of skin lightening drugs 8 weeks prior to treatment, Skin type 5 of the Fitzpatrick scale, Patients exposed to direct UV light, Patients under 16 years old

Intervention groups

A group of 30 patients are treated with single pass plasma and another group of 30 patients are treated with plasma and Alexandrite Signasure laser

Main outcome variables

Evaluation of the responsiveness of pigmented lesions to plasma with and without alexandrite laser

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230103057039N1**

Registration date: **2023-04-06, 1402/01/17**

Registration timing: **retrospective**

Last update: **2023-04-06, 1402/01/17**

Update count: **0**

Registration date

2023-04-06, 1402/01/17

Registrant information

Name

Mahin Fathi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4613 8218

Email address

mahin.pt86@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-27, 1401/11/07

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the plasma effect with and without

alexandrite laser in the treatment of freckles in patients referred to the clinics affiliated with Tehran Medical Sciences Azad University in 2022-2023

Public title

Evaluation of the efficacy of laser and plasma in the treatment of freckles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having freckles Skin types 1 to 4 on the Fitzpatrick scale Patient over 16 years old

Exclusion criteria:

Taking skin lightening drugs 8 weeks before treatment Fitzpatrick scale type 5 skin People who are directly exposed to UV light People under 16 years old

Age

From **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluation of the results of the interventions is done by a dermatologist and this study is blinded by her

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research Faculty of Medicine, Tehran Islamic Azad University of Medical Sciences

Street address

Headquarters Building of Islamic Azad University of Medical Sciences Tehran, Corner of Ice Flower Street, Ayeneh Boulevard, Dr. Shariati Street

City

Tehran

Province

Tehran

Postal code

1949635881

Approval date

2022-12-26, 1401/10/05

Ethics committee reference number

IR.IAU.TMU.REC.1401.322

Health conditions studied

1

Description of health condition studied

Patients with freckles

ICD-10 code

L81.2

ICD-10 code description

Freckles

Primary outcomes

1

Description

Degree of pigmentation

Timepoint

Before and after the intervention

Method of measurement

Based on the reduction of pigmentation: Weak, Medium, Excellent

2

Description

Side effects

Timepoint

A month after the treatment is finished

Method of measurement

Ask the patient

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: A group of 30 patients with Fitzpatrick skin type 1 to 4 who had no history of using topical lightening drugs from 8 weeks before treatment, without sexual restriction, over 16 years old, will be treated with plasma single pass. The amount of skin pigmentation in two stages before and after treatment is determined. The response to treatment will be complete loss of lesions (recovery above 80%).

Category

Treatment - Devices

2

Description

Second group of intervention: A group of 30 patients with Fitzpatrick skin type 1 to 4 who had no history of using topical lightening drugs from 8 weeks before treatment, without sexual restriction, over 16 years old will be treated with plasma single pass with a single pass laser shot with a wavelength of 755 nm with a wavelength of 5 mm and Pulse duration of 0.5 millisecond with Fluence = 20 J/cm² for skin type 3 and 4 /Fluence = 24 J/cm² for skin type 1 and 2 in single pass. The amount of skin pigmentation in two stages before and after treatment is determined. The response to treatment will be complete loss of lesions (recovery above 80%).

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Farhikhtegan Hospital

Full name of responsible person

Dr Setareh Tehrani

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

Dr Setareh Tehrani

Street address

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Fax**Email**

Int.affairs@iautmu.ac.ir

Web page address

<http://tms.iau.ir/ghods>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Farshad Hashemian

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Mahin Fathi

Position

Medical Intern

Latest degree

Bachelor

Other areas of specialty/work

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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

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

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

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

Data Dictionary

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