

# 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/cm<sup>2</sup> for skin type 3 and 4 /Fluence = 24 J/cm<sup>2</sup> 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

**Street address**

University Square, The northern end of Satari

**City**

Tehran

**Province**

Tehran

**Postal code**

1477899676

**Phone**

+98 21 4486 7262

**Fax**

+98 21 4484 5171

**Email**

farhikhteganhospital@gmail.com

### 2

#### Recruitment center

**Name of recruitment center**

Azad University Quds Clinic

**Full name of responsible person**

Dr Setareh Tehrani

**Street address**

No. 1 - Qods Town (West) - End of Phase 6 -Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1495/19395

**Phone**

+98 21 8807 8388

**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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1949635881

**Phone**

+98 21 2660 2643

**Email**

Int.affairs@iautmu.ac.ir

**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**

General Practitioner

**Street address**

No. 2, Arash street, Park Ave, Hamila Blvd, Punak

**City**

Tehran

**Province**

Tehran  
**Postal code**  
1469696006  
**Phone**  
+98 21 4613 8218  
**Email**  
mahin.pt86@yahoo.com

## Person responsible for scientific 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**  
General Practitioner  
**Street address**  
No.7, Arash street, Park Ave, Hamila Blv, Punak  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1469696006  
**Phone**  
+98 21 4613 8218  
**Email**  
mahin.pt86@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**

Mahin Fathi  
**Position**  
Medial Intern  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
General Practitioner  
**Street address**  
No.2, Arash street, Park Ave, Hamila Blv, Punak  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1469696006  
**Phone**  
+98 21 4613 8218  
**Email**  
mahin.pt86@yahoo.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

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