

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the efficacy of Alexandrite laser therapy versus medical therapy for the treatment of infraorbital dark circles in patients of dermatology clinic

#### Protocol summary

##### Study aim

Comparison of the Efficacy of Pharmacological Therapy and Alex Laser Therapy in Treating Dark Circles Under the Eyes in Patients Complaining of Dark Circles at a Dermatology Clinic in Tehran in 2024.

##### Design

This clinical trial consists of two comparative groups undergoing treatment with laser therapy and topical medication, featuring parallel groups and a single-blind design. The allocation of participants to the groups was performed non-randomly. This is a Phase 2 study involving a total of 102 patients.

##### Settings and conduct

This clinical trial will involve 102 patients with periorbital hyperpigmentation, divided into two groups of 51. Participants will be unaware of each other's conditions. One group will receive four sessions of Alexandrite laser therapy at one-month intervals, while the other group will apply a modified Kligman formula nightly for six months, consisting of 0.1% betamethasone, 5% hydroquinone, and 0.05% tretinoin. The degree of hyperpigmentation will be assessed before and after treatment. Additionally, patient satisfaction with both treatment modalities will be evaluated and compared.

##### Participants/Inclusion and exclusion criteria

In general, patients presenting with complaints of dark circles under the eyes at the dermatology clinic who consent to participate in the study will be included. Those who express unwillingness to continue their participation or experience a severe medical adverse event will be withdrawn from the study.

##### Intervention groups

In this study, two types of interventions will be conducted in two distinct groups for the treatment of infraorbital hyperpigmentation. One group will undergo treatment with Alexandrite laser for a total of four sessions in the under-eye area, while the other group will

utilize topical medications nightly for a duration of six months.

##### Main outcome variables

Efficacy comparison of methods for infraorbital hyperpigmentation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20241018063404N1**

Registration date: **2025-01-08, 1403/10/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2025-01-08, 1403/10/19**

Update count: **0**

##### Registration date

2025-01-08, 1403/10/19

##### Registrant information

##### Name

Sama Khoraminejad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7788 2168

##### Email address

s.khoraminejad@iau.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-11-21, 1403/09/01

##### Expected recruitment end date

2025-08-01, 1404/05/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the efficacy of Alexandrite laser therapy versus medical therapy for the treatment of infraorbital dark circles in patients of dermatology clinic

**Public title**

Comparison of the efficacy of laser therapy versus medical therapy for the treatment of infraorbital dark circles

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients having darkness under the eyes referring to the skin clinic Consent to participate in the study

**Exclusion criteria:**

Refusal to continue participating in the study Severe medical complication

**Age**

From **18 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **102**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, a single-blind method has been used. In this approach, participants are unaware of the group allocation. This design was intentionally implemented to prevent any potential bias or psychological influence in the assessment of outcomes.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee****Name of ethics committee**

Research Ethics Committees of Tehran Islamic Azad University Of Medical Sciences

**Street address**

3th Floor, No. 48, Shahid Maleki Alley, West 160 St., Rashid Ave., Tehran Pars

**City**

Tehran

**Province**

Tehran

**Postal code**

1653959564

**Approval date**

2024-10-09, 1403/07/18

**Ethics committee reference number**

IR.IAU.TMU.REC.1403.302

**Health conditions studied**

1

**Description of health condition studied**

Infraorbital dark circles

**ICD-10 code****ICD-10 code description****Primary outcomes**

1

**Description**

Infraorbital pigmentation score

**Timepoint**

Measurement of under-eye pigmentation was conducted at the onset of the study (prior to the initiation of the intervention) and again six months following the commencement of treatment.

**Method of measurement**

Measurement of pigmentation device; Questionnaire

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention Group One: The first intervention group consists of 51 individuals who presented with complaints of dark circles under the eyes at Dr. Tehrani's dermatology clinic in Tehran. This group will receive treatment using the Alexandrite laser from Cynosure Elite, an American-made device operating at a wavelength of 755 nm. Participants in this group will undergo treatment over four sessions, spaced 1.5 months apart. During the treatment period, participants will be permitted to use only under-eye sunscreen.

**Category**

Treatment - Devices

## 2

### Description

Intervention group Two: Intervention Group Two: The second intervention group comprises 51 individuals who presented with complaints of dark circles under the eyes at Dr. Tehrani's dermatology clinic in Tehran. This group will receive treatment with a modified formulation of the Kligman formula, consisting of a 0.1% betamethasone cream, a 5% hydroquinone cream and a 0.05% tretinoin cream. Participants are required to apply a lentil-sized amount of this topical combination under the eyes every night for a duration of six months. Throughout the treatment period, participants will be permitted to use only the prescribed medications and an under-eye sunscreen.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dermatology clinic of Dr. Tehrani

##### Full name of responsible person

Sepideh Tehrani

##### Street address

Unit 19, 4th Floor, Building 2, Corner of Sarv Alley,  
Between Mirdamad and Zafar Streets, Jordan Street,  
Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1968645744

##### Phone

+98 21 8878 8919

##### Email

Tehrani۴۲۶۴۳@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Masoud Parsania

##### Street address

University of Azad Medical Sciences, Corner of Gol  
Yakh Street and Ayneh Boulevard, Amir Pabargah  
Street, Qolhak Intersection, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1949635881

##### Phone

+98 21 2642 2660

##### Email

alisamiee777879@gmail.com

##### 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

1

##### 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

Islamic Azad University

##### Full name of responsible person

Sama Khoraminejad

##### Position

Medical Intern

##### Latest degree

A Level or less

##### Other areas of specialty/work

General Practitioner

##### Street address

3th Floor, No. 48, Shahid Maleki Alley, West 160 St.,  
Rashid Ave., Tehran Pars

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##### Province

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##### Postal code

1653959564

##### Phone

+98 21 7788 2168

##### Fax

##### Email

s2000.edu.khoram@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

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##### Position

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##### Latest degree

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**Person responsible for updating data**

**Contact**

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**Latest degree**

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**Email**

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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**

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

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The individual data of participants in this study will be shared only after ensuring that the identities of individuals are rendered unidentifiable, thereby preserving the privacy of all participants.

**When the data will become available and for how long**

The dissemination of these documents/data files will occur upon the complete conclusion of the research project. In the event that the project is published as a manuscript, access to the data will be granted following the completion of the publication process, and will remain available for a period of up to two years after the article's publication.

**To whom data/document is available**

Due to the practical relevance of the project's subject matter in the fields of medicine, industry, and aesthetics, access will be granted to individuals who submit requests and are approved and deemed qualified by the project team.

**Under which criteria data/document could be used**

Any utilization of the data from this study must be coordinated with the project team responsible for its execution and accompanied by a written permission statement from the research team to ensure the preservation of publication rights.

**From where data/document is obtainable**

Applicants may contact us via email at the following address (or at a subsequently provided address in the event of any changes): s2000.edu.khoram@gmail.com.

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

Initially, you are required to introduce yourself and your research group in your email. Following this, please provide a comprehensive description of how the data will be utilized and the specific methodologies involved. It is essential to clearly and explicitly articulate the objectives of using the data. Subsequently, necessary arrangements will be coordinated with you by the project team.

**Comments**