Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 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 Those who express unwillingness to continue their participation or experience a severe medical adverse event will be withdrawn from the study.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

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1968645744

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+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

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Province
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1949635881

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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

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

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Person responsible for scientific inquiries

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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