

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Assessing the effectiveness of the combination therapy with Erbium laser and PRP (Platelet Rich Plasma) in the treatment of periorbital dark circles

Protocol summary

Study aim

Determining the effectiveness and side effects of using PRP with Erbium laser in the treatment of dark circles

Design

The aim of this study was to evaluate the efficacy and side effects of using Erbium laser and PRP (Intervention group) in comparison Erbium laser and physiological serum (control group) in the treatment of dark circles in 32 patients which have been entered into the study by block randomization method. In each session immediately after the laser therapy, one side of the patient's face, PRP, and the other side of the face, the physiologic serum was applied locally to the dark circles for one hour. This procedure is repeated 3 times at intervals of 4 weeks.

Settings and conduct

This design is done at the skin and stem cell research center of Tehran university of medical sciences and without the patient's knowledge about the intervention groups, in the dark area around the eyes, after the Erbium laser, one side of the face of PRP and other side for blinding is used of the physiology serum the dark circles.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18-50 years old; the cause of darkness, structural and reducing fat in this area is not. Exclusion criteria: pregnancy or breastfeeding; active infection in face; history of cancer.

Intervention groups

First intervention group: the circular darkness on one side of the face is treated with Erbium laser and PRP. Second intervention group: the dark circles of the eye on other side of the face is treated with Erbium laser and physiological serum.

Main outcome variables

Melanin Index; side effects; patient's satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001159N28**

Registration date: **2020-07-20, 1399/04/30**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-20, 1399/04/30**

Update count: **0**

Registration date

2020-07-20, 1399/04/30

Registrant information

Name

Mohamad Ali Nilforoushzadeh

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical sciences

Country

Iran (Islamic Republic of)

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+98 21 2220 5158

Email address

sdIrc@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effectiveness of the combination therapy with Erbium laser and PRP (Platelet Rich Plasma) in the treatment of periorbital dark circles

Public title

The effectiveness of PRP and Erbium laser in the treatment of dark circles around the eyes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The cause of darkness, structural and reducing fat in this area is not Age between 18 and 50 years old

Exclusion criteria:

Active infection in the face Pregnancy and breastfeeding
History of cancer

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **32**

More than 1 sample in each individual

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

A half face will be considered as the control group and one half as an intervention group.

Randomization (investigator's opinion)

Randomized

Randomization description

In this method, block randomization is used. 32 patients will be included in the study by available sampling method based on inclusion and exclusion criteria. Each patient was considered as a block and their left and right eyes were randomly assigned to two groups using cards with study groups written on them.

Blinding (investigator's opinion)

Single blinded

Blinding description

On both sides of the face in the dark area around the patient's eye, an airbag laser will be performed, and without the patient knowing the location of each intervention group, after laser therapy, PRP will be used on one side of the face and physiological serum on the opposite side.

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

Tehran University of Medical Sciences, Keshavarz blvd.

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Tehran

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Postal code

1417653761

Approval date

2019-01-30, 1397/11/10

Ethics committee reference number

IR.TUMS.VCR.REC.1397.870

Health conditions studied**1****Description of health condition studied**

Eye dark circles

ICD-10 code

-

ICD-10 code description

-

Primary outcomes**1****Description**

Preorbital hyperpigmentation

Timepoint

Session 0, 4 and 6 during treatment and 3 months after treatment

Method of measurement

Intensity of the darkening of the skin around the eyes compared to other areas of the face with Mexameter device.

2**Description**

Satisfaction amount

Timepoint

After completion of treatment

Method of measurement

Comparison of reduction preorbital hyper pigmentation by patient , before and after treatment According to schedule (score 0 to 10)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: (one side of the face) The dark area around the eye is first treated with Erbium laser, and then physiological serum is applied topically on the site for one hour. This method is repeated 3 times at intervals of 4 weeks.

Category

Treatment - Other

2

Description

Intervention group: (other side of the face) The dark area around the eye is first treated with Erbium laser, and then PRP is applied topically on the site for one hour. This method is repeated 3 times at intervals of 4 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Skin and Stem cell Research Center of Tehran University of Medical Sciences

Full name of responsible person

Shiva Alavi

Street address

No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran

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1937957511

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shiva.alavi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Abbas Ali Karimi

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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

Skin and Stem cell Research Center of Tehran University of Medical Sciences

Full name of responsible person

Shiva Alavi

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Skin and Stem cell Research Center of Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Researcher

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Ph.D.

Other areas of specialty/work

Medical Biology

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable