

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Comparing the safety and effectiveness of the treatment of dark circles around the eyes by platelet-rich plasma-conditioned medium derived from Wharton jelly mesenchymal stem cells with Q-Switched laser: a randomized clinical trial study.

Protocol summary

Registration timing: **prospective**

Study aim

Comparing the safety and effectiveness of the treatment of dark circles around the eyes by platelet-rich plasma-conditioned medium derived from Wharton jelly mesenchymal stem cells with Q-Switched laser: a randomized clinical trial study

Last update: **2024-06-08, 1403/03/19**

Update count: **0**

Registration date

2024-06-08, 1403/03/19

Design

Clinical trial with one control group and one intervention group, with parallel groups, single-blind, Non-random assignment to intervention and control groups, phase 1-2 on 10 patients with periorbital dark circles

Registrant information

Name

Sona Zare

Name of organization / entity

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

Country

Iran (Islamic Republic of)

Phone

+98 21 2665 7438

Email address

sonazarebio@gmail.com

Settings and conduct

The intervention site is Skin and Stem Cell Research Center of Tehran University of Medical Sciences.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18-65 years; patients with periorbital dark circles. Exclusion criteria: Active infection on face, pregnancy, Breastfeeding, history of cancer, structural darkening or loss of fat around the eyes

Expected recruitment start date

2024-06-14, 1403/03/25

Expected recruitment end date

2024-09-15, 1403/06/25

Intervention groups

Intervention group: patients are treated with Q-switched Nd:YAG 1064nm laser, 0.5 cc conditioned medium injection and 0.5cc PRP injection three times with four weeks interval. Control group: patients are treated with Q-switched Nd:YAG 1064nm laser and 0.5cc PRP injection three times with four weeks interval.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Periorbital dark circles; patient's satisfaction

Trial completion date

empty

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N40**

Registration date: **2024-06-08, 1403/03/19**

Scientific title

Comparing the safety and effectiveness of the treatment of dark circles around the eyes by platelet-rich plasma-

conditioned medium derived from Wharton jelly mesenchymal stem cells with Q-Switched laser: a randomized clinical trial study.

Public title

Comparison of the treatment of dark circles around the eyes by platelet-rich plasma-conditioned medium with Q-Switched laser

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age from 18 to 65 years Patient with periorbital dark circles

Exclusion criteria:

Active infection on face Pregnancy Breastfeeding History of cancer Structural dark circles or under eye loss of fat

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The study will be done as single-blind and only the outcome evaluator will be unaware of the treatment method. The patient and the doctor will have enough information about the treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Working Group/Ethics Committee in Research Faculty of Medicine-Tehran University of Medical Sciences

Street address

Ethics Committee, Technology and Research office, Ghods st., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2023-11-27, 1402/09/06

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.471

Health conditions studied

1

Description of health condition studied

Periorbital dark circles

ICD-10 code

H02.71

ICD-10 code description

Chloasma of eyelid and periocular area

Primary outcomes

1

Description

Periorbital dark circles

Timepoint

Before and 3 months after treatment

Method of measurement

severity of under eye dark halos in comparison to the rest of the face, using mexameter device.

Secondary outcomes

1

Description

Satisfaction rate

Timepoint

Three months after the last meeting

Method of measurement

comparing the severity of periorbital dark circles, before and after treatment (score from 0 - 10)

Intervention groups

1

Description

Intervention group: patients are treated with Q-switched Nd:YAG 1064nm laser, 0.5 cc conditioned medium injection and 0.5cc PRP injection three times with four weeks interval.

Category

Treatment - Other

2

Description

Control group: patients are treated with Q-switched Nd:YAG 1064nm laser and 0.5cc PRP injection three times with four weeks interval.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**Skin and Stem cell Research Center Clinic, Tehran
University of Medical Sciences**Full name of responsible person**

Mohammad Ali Nilforoushzadeh

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No 4, Maryam Alley, South Kamraniyeh Street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Ali Akbari Sari

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Chancellor for Research and Technology, corner of
Quds Street, Keshavarz Boulevard**City**

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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**

Sona Zare

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Cellular and Molecular Biology

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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

Subspecialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

Skin and Stem cell Research Center of Tehran
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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Cellular and Molecular 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