Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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

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

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

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

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 laserand 0.5cc PRP injection three times with four weeks interval.

Main outcome variables
Periorbital dark circles; patient's satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200127046282N40**
Registration date: **2024-06-08, 1403/03/19**
Registration timing: **prospective**

Last update: **2024-06-08, 1403/03/19**
Update count: **0**

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

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

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-14, 1403/03/25

Expected recruitment end date
2024-09-15, 1403/06/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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 laserand 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Akbari Sari
Street address
Central University Organization, sixth floor, Vice Chancellor for Research and Technology, corner of Quds Street, Keshavarz Boulevard
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vcr@tums.ac.ir
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

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Professor
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Person responsible for updating data

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Full name of responsible person
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Position
Researcher

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