Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effectiveness of nanofat along with Stromal vascular fraction (SVF) and Platelet Rich plasma (PRP) in facial rejuvenation and dark circles around the eyes

Protocol summary

Study aim
Evaluation of the effectiveness of nanofat along with Stromal vascular fraction (SVF) and Platelet Rich plasma (PRP) in facial rejuvenation and dark circles around the eyes

Design
Clinical trial with two control groups and one intervention group, with parallel groups, single blind, non-random assignment to intervention and control groups, phase I-II، 30 patients with dark circles around the eyes

Settings and conduct
The intervention site is the Skin and Stem Cell Research Center of Tehran University of Medical Sciences. In the intervention group, patients are treated with nanofat, SVF and PRP injections, and in the control groups, patients are only treated with nanofat alone and nanofat and PRP. In this study, blinding has been done and the person analyzing the data is not aware of the type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age from 18 to 65 years, patient with periorbital dark circles, the patient has wrinkles.
Exclusion criteria: Active infection on face, pregnancy, breastfeeding, history of cancer, structural dark circles or under eye loss of fat

Intervention groups
Control group 1: Patients are treated with nanofat injections in the whole face and under the eyes in one session. Control group 2: Patients are treated with nanofat and PRP injections in the whole face and under the eyes in one session. Intervention group: Patients are treated with nanofat, SVF and PRP injections in the whole face and under the eyes in one session.

Main outcome variables
periorbital dark circles, amount of wrinkles

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200127046282N31**
Registration date: **2023-05-18, 1402/02/28**
Registration timing: **prospective**

Last update: **2023-05-18, 1402/02/28**
Update count: **0**

Registration date
2023-05-18, 1402/02/28

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
2023-05-20, 1402/02/30

Expected recruitment end date
2023-08-06, 1402/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of nanofat along with Stromal vascular fraction (SVF) and Platelet Rich plasma (PRP) in facial rejuvenation and dark circles around the eyes

Public title
Evaluation of the effect of nanofat along with SVF and PRP in facial rejuvenation and dark circles around the eyes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age from 18 to 65 years Patient with periorbital dark circles The patient has wrinkles

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: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The patient and the doctor will have enough information about the treatment due to the sampling of fat tissue and blood. After transplantation and in the follow-up phase, all participants will be examined by a medical staff who is blinded to this study and group allocation. At this stage, this person does not know the type of intervention in each group. Therefore, the study will be single blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of School of Medicine-Tehran University of Medical Sciences

Street address
Room 604, 6th Floor, Tehran University of Medical Sciences Central Building, Qods St. intersection, Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2023-04-09, 1402/01/20

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.009

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

2

Description of health condition studied
Skin aging

ICD-10 code
L90.9

ICD-10 code description
Atrophic disorder of skin, unspecified

Primary outcomes

1

Description
Periorbital dark circles

Timepoint
Before, during the treatment and 3 months after intervention

Method of measurement
severity of under eye dark halos in comparison to the rest of the face, using Mexameter device

2

Description
The amount of wrinkles

Timepoint
Before treatment and six months after intervention

Method of measurement
Visio face

Secondary outcomes

1

Description
Satisfaction rate
Timepoint
After completing the intervention
Method of measurement
comparing the severity of periorbital dark circles, before and after treatment (score from 0 - 10)

2

Description
Inflammation
Timepoint
Half an hour after the end of the intervention
Method of measurement
Questionnaire and visit

3

Description
Intensity of pain
Timepoint
At the time of the intervention
Method of measurement
Questionnaire and visit

Intervention groups

1

Description
Control group 1: In one session, patients are treated with 5 cc of nanofat injection (prepared at the research center clinic) in the whole face and under the eyes.
Category
Treatment - Other

2

Description
Control group 2: Patients are treated in one session by injecting 5 cc of nanofat (prepared in the research center clinic) and 2 cc of PRP (prepared in the research center laboratory) in the whole face and under the eyes.
Category
Treatment - Other

3

Description
Intervention group: In one session, patients were treated by injecting 5 cc of nanofat (prepared in the clinic of the research center), 1 cc of adipose tissue SVF (prepared in the clean room of the research center) and 1 cc of PRP (prepared in the laboratory of the research center) in They are placed on the whole face and under the eyes.
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
Street address
No 4, Maryam Alley, South Kamraniyeh Street
City
Tehran
Province
Tehran
Postal code
1937957511
Phone
+98 21 2665 7438
Email
nilforoosh@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotoohi
Street address
Central University Organization, sixth floor, Vice Chancellor for Research and Technology, corner of Quds Street, Keshavarz Boulevard
City
Tehran
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Postal code
1937957511
Phone
+98 21 8163 3698
Email
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
Street address
No 4, Maryam Alley, South Kamraniyeh Street
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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
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Full name of responsible person
Sona Zare
Position
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Latest degree
Ph.D.
Other areas of specialty/work
Cellular and Molecular Biology
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1937957511
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sonazarebio@gmail.com

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