

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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

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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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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
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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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Other areas of specialty/work

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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