

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 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

##### Province

Tehran

##### 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

1937957511

**Phone**

+98 21 2665 7438

**Email**

nilforoosh@sina.tums.ac.ir

**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 updating data****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**

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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

**Street address**

No 4, Maryam Alley, South Kamraniyeh Street

**City**

Tehran

**Province**

Tehran

**Postal code****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