

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Comparison of therapeutic effect of nanofat injection alone and nanofat with Stromal Vascular Fraction (SVF), Platelet Rich Plasma (PRP) and ND-YAG laser in improving darkening and rejuvenation under the eye

#### Protocol summary

##### Study aim

Comparing the therapeutic effects of nanofat injection alone and nanofat with three interventions 1) vascular stromal cells (SVF), 2) platelet-rich plasma (PRP) and 3) ND-YAG laser on under eye dullness and rejuvenation

##### Design

Clinical trial with one control group and three intervention groups, with parallel groups, one-way blind (outcome assessor), randomized based on random number table, phase 1 on 30 patients with periorbital hyperpigmentation

##### Settings and conduct

The study site is the Clinic of Skin and Stem Cell Research Center of Tehran University of Medical Sciences. In this study will be subjected to blinding, and the outcome assessor will be unaware of the treatment type. There are three intervention groups and one control group. Two sessions of treatment will be performed with an interval of one month

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: cases subjected to under eyes' dullness and wrinkles and in need for rejuvenation base on dermatologist's diagnosis, Exclusion criteria: Use of any treatment to eliminate dullness and rejuvenation under the eyes during recent three months, in case of collagen and vascular diseases , taking steroids or anti-immune drugs, pregnancy and lactation.

##### Intervention groups

Patients are randomly divided into 1 control group and 3 intervention groups. In the control group, 15 patients will be treated with nanofat injection. In the intervention groups, 15 patients are divided into three groups of 5: one group will receive nanofat and SVF injection, one group will receive nanofat and PRP injection, and the other group will receive nanofat and Nd; YAG laser.

##### Main outcome variables

dullness rate ; Rejuvenation rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200127046282N21**

Registration date: **2023-01-22, 1401/11/02**

Registration timing: **retrospective**

Last update: **2023-01-22, 1401/11/02**

Update count: **0**

##### Registration date

2023-01-22, 1401/11/02

##### 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

2022-07-06, 1401/04/15

##### Expected recruitment end date

2022-09-21, 1401/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of therapeutic effect of nanofat injection alone and nanofat with Stromal Vascular Fraction (SVF), Platelet Rich Plasma (PRP) and ND-YAG laser in improving darkening and rejuvenation under the eye

**Public title**

Effect of nanofat injection alone and combined with SVF, PRP and ND-YAG laser on treatment of periorbital dark circles and rejuvenation

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Under eye wrinkles, dark circles and need for rejuvenation based on dermatologist's diagnosis No medical treatment for under eye's dark circles, wrinkles and rejuvenation in recent 2 months Patients' Informed consent Ages under 50 and over 18 years

**Exclusion criteria:**

Skin lesions and diseases such as skin cancer Wart Skin infection Collagen and vascular diseases Pregnancy and lactation Taking steroids or anti-immune drugs

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

1

**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**

Patients and physician will know the type of treatment, but the outcome assessor will not know the patient's type of treatment. Therefore, it will be performed as a single blind study.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

**Street address**

Tehran University of Medical Sciences, Keshavarz blvd.

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Approval date**

2022-03-09, 1400/12/18

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1400.1487

**Health conditions studied****1****Description of health condition studied**

Darkening under the eye

**ICD-10 code**

L81.9

**ICD-10 code description**

disorder of pigmentation, unspecified

**Primary outcomes****1****Description**

Darkness under the eyes

**Timepoint**

prior to treatment, three and six months after the last treatment session

**Method of measurement**

VisioFace device

**2****Description**

under eye rejuvenation

**Timepoint**

prior to treatment, three and six months after the last treatment session

**Method of measurement**

Visioface

**3****Description**

safety of treatment method

**Timepoint**

in the Injection session and one week after each session

**Method of measurement**

Questionnaire and clinical observation

**Secondary outcomes**

## 1

### **Description**

Pain Intensity

### **Timepoint**

Injection session

### **Method of measurement**

Questionnaire (scoring from 1 to 10) and visual pain questionnaire

## 2

### **Description**

Patient satisfaction

### **Timepoint**

prior to treatment, three months and six months after the last treatment session

### **Method of measurement**

Standard questionnaires visual analogue scale (VAS)

## 3

### **Description**

Inflammation

### **Timepoint**

1-5 hours after injection

### **Method of measurement**

In this study, the inflammation rate around the eyes (with scores of 0 and 1), will be performed by a physician.

## **Intervention groups**

### 1

#### **Description**

1 cc of nanofat with 1 cc of vascular stromal cells (SVF) extracted from adipose tissue will be injected in 2 sessions with an interval of 1 month.

#### **Category**

Treatment - Other

### 2

#### **Description**

Second intervention group: 1 cc of nanofat with 1 cc of platelet-rich plasma (PRP) extracted from blood will be injected in 2 sessions with an interval of 1 month.

#### **Category**

Treatment - Other

### 3

#### **Description**

Third intervention group: 1 cc of Nanofat after ND-YAG laser is injected in 2 sessions with an interval of 1 month.

#### **Category**

Treatment - Other

### 4

#### **Description**

Control group: 1 cc of Nanofat is injected in 2 sessions

with an interval of 1 month.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Clinic of Skin and Stem cell Research Center of Tehran University of Medical Sciences

##### **Full name of responsible person**

Masoumeh Roohaninasab

##### **Street address**

No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1937957511

##### **Phone**

+98 21 2665 7438

##### **Email**

rohaninasab.m@iums.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.i

#### **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

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2665 7438

**Email**

masoomehrohani@yahoo.com

**Person responsible for general inquiries****Contact****Name of organization / entity**Skin and Stem Cell Research Center, 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, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2665 7438

**Email**

sonazarebio@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**Skin and Stem Cell Research Center, 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, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2665 7438

**Email**

sonazarebio@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**Skin and Stem Cell Research Center, Tehran  
University of Medical Sciences**Full name of responsible person**

Masoumeh Roohaninasab

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

No 4, Maryam Alley, South Kamraniyeh Street, Tehran

**City**

Tehran

**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