

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 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

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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

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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

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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

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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

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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, Tehran
University of Medical Sciences**Full name of responsible person**

Masoumeh Roohaninasab

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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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