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 nanoft 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
Ḍarkening 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
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No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran
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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.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

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

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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