Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of stromal vascular fraction gel (svf+non cross-linked hyaluronic acid)on the periorbital rejuvenation and comparig it with svf injection alone

Protocol summary

Study aim
To compare the efficacy of SVF alone versus SVF combined with hyaluronic acid in periorbital rejuvenation

Design
Randomized, double-blind, phase 2 clinical trial, split-face design on 10 patients. Randomization was performed using the RAND function in Excel

Settings and conduct
The study is conducted at the Dermatology Clinic of Hazrat Fatemeh Specialized Hospital. After obtaining informed consent, adipose tissue is harvested from the abdominal area and SVF is prepared using a mechanical method. In a single session, intradermal injections are performed: 2 cc SVF is injected on one periorbital side, and a mixture of 1 cc SVF with 1 cc hyaluronic acid on the opposite side. Side allocation is randomized. The study is double-blind; both the patient and the outcome assessors are unaware of the treatment assigned to each side.

Participants/Inclusion and exclusion criteria
: Inclusion criteria: Individuals aged 20 to 65 with signs of periorbital aging. Exclusion criteria: Active infection, autoimmune diseases, use of immunosuppressants or anticoagulants, pregnancy, and lactation

Intervention groups
Group 1: Injection of 2 cc SVF around the eye. Group 2: Injection of a combination of 1 cc SVF and 1 cc hyaluronic acid on the opposite side. Both groups receive active intervention to compare their efficacy.

Main outcome variables
Periorbital skin changes measured by Visioface device; GAIS improvement score by patient and dermatologists; patient satisfaction (Patient Global Assessment Score); physician satisfaction (Physician Global Assessment Score); recording of adverse events including bruising, infection, hypersensitivity, diplopia.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220322054341N3**
Registration date: **2025-10-22, 1404/07/30**
Registration timing: **registered_while_recruiting**

Last update: **2025-10-22, 1404/07/30**
Update count: **0**
Registration date
2025-10-22, 1404/07/30

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-09-22, 1404/06/31
Expected recruitment end date
2025-11-21, 1404/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of stromal vascular fraction gel (svf+non cross-linked hyaluronic acid)on the periorbital rejuvenation and comparig it with svf injection alone

Public title
The effect of svf in periorbital rejuvenation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
participants aged 20 to 65 years presenting with age-related periorbital changes (including dark circles, periorbital wrinkles, decreased skin firmness, and under-eye laxity), who provide informed consent and are able to attend follow-up visits, will be included in the study.

Exclusion criteria:
Active inflammation or herpetic infection at the procedure site, collagen vascular diseases, or warts use of corticosteroids, immunosuppressive, anticoagulant, or antiplatelet medications platelet function disorders or thrombocytopenia pregnancy or lactation

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **10**
More than 1 sample in each individual
Number of samples in each individual: **2**
Complaints of dark circles, fine wrinkles, and laxity of the periorbital skin

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The injection of stromal vascular fraction (SVF), stromal vascular fraction (SVF)and normal saline was done with syringes of the same shape, the contents of which are not known, and the patient does not know which treatment group he is in. Also, the doctor evaluating the results and the statistician are blinded to the treatment group of the patient.

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of School of Medicine, Iran University of medical sciences

Street address
School of medicine, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran

City
tehran

Province
Tehran

Postal code
1449614535

Approval date
2025-03-20, 1403/12/30

Ethics committee reference number
IR.IUMS.FMD.REC.1404.003

Health conditions studied

1

Description of health condition studied
periorbital aging/wrinkles/hyperpigmentation

ICD-10 code
L81.4

ICD-10 code description
Other melanin hyperpigmentation

Primary outcomes

1

Description
Pigmentation (color of the lesion)

Timepoint
1 and 3 months after the treatment

Method of measurement
Skin analysis using the VisioFace system/Patient satisfaction (Patient Global Assessment Score/Physician satisfaction (Physician Global Assessment Score

2

Description
wrinkle

Timepoint
1 and 3 months after the treatment

Method of measurement
Skin analysis using the VisioFace system/Patient satisfaction (Patient Global Assessment Score/Physician satisfaction (Physician Global Assessment Score

Secondary outcomes

1

Description
Complications
Timepoint
1 and 3 months after the treatment
Method of measurement
Using a checklist containing treatment complications including pain, erythema and edema

Intervention groups

1

Description
Intervention group: Intervention Group 1: Injection of 2 cc stromal vascular fraction (SVF) cells extracted from abdominal fat into one side of the periocular area. Fat harvesting involves 40 cc abdominal fat aspiration, followed by centrifugation at 1200g for 3 minutes, nanofat separation with physical filters, and a second centrifugation at 2000g for 3 minutes to isolate the SVF layer. Injection is intradermal, at 1 cm intervals, in a single session.
Category
Treatment - Other

2

Description
.Intervention Group 2: Injection of a combination of 1 cc SVF (prepared as above) and 1 cc non-crosslinked hyaluronic acid gel (Luxiva) into the contralateral periocular area. The mixture is injected intradermally at 1 cm intervals, in a single session.Both interventions are randomly assigned to either the left or right side. Patients and evaluators (two dermatologists) are blinded to the type of injection on each side (double-blind
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Fatemeh Hospital
Full name of responsible person
Masoomeh Rohaninasab
Street address
Seyed Jamaleddin Asadabadi Street, 21st Street, Next to Shafagh Park, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Masoomeh Roohaninasab
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Office of Vice President for International Affairs, Iran University of Medical Sciences (IUMS), Shahid Hemmat Highway, Tehran, IRAN
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Masoumeh Roohaninasab
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
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Person responsible for updating data

Contact

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Full name of responsible person

Elahe khoshnoo

Position

Resident

Latest degree

Medical doctor

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

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available