

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Investigating the effect of SVF gel (Stromal Vascular Fraction (SVF) + non cross-linked hyaluronic acid) on the periorbital rejuvenation and comparing it with SVF injection alone

Protocol summary

Study aim

Investigating the effect of SVF gel (Stromal Vascular Fraction (SVF) + non cross-linked hyaluronic acid) on the periorbital rejuvenation and comparing it with SVF injection alone

Design

Clinical trial with a control group and an intervention group, with parallel groups, single-blind, non-random assignment to intervention and control groups, phase 1, 10 patients with wrinkles 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 SVF Gel, and in the control group, patients are treated with SVF only. Blinding was performed in this study and the patient was not informed of the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 65 years, patient must have aging around the eyes. Inclusion criteria: Active infection in the facial area, pregnancy, breastfeeding, history of cancer.

Intervention groups

In the intervention group, patients are injected with 1 cc of SVF and 1 cc of non-cross-linked hyaluronic acid on one side of the eye area in one session, and in the control group, patients are injected with 2 cc of SVF on one side of the eye area in one session.

Main outcome variables

amount of wrinkles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N59**

Registration date: **2025-12-01, 1404/09/10**

Registration timing: **prospective**

Last update: **2025-12-01, 1404/09/10**

Update count: **0**

Registration date

2025-12-01, 1404/09/10

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

2025-12-21, 1404/09/30

Expected recruitment end date

2026-02-19, 1404/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of SVF gel (Stromal Vascular Fraction (SVF) + non cross-linked hyaluronic acid) on the

periorbital rejuvenation and comparing it with SVF injection alone

Public title
Review of Stromal Vascular Fraction Gel injections for eye rejuvenation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age from 18 to 65 years The patient has aging around the eyes.
Exclusion criteria:
Active infection in the facial area Pregnancy Breastfeeding History of cancer

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
1

Groups that have been masked

- Participant

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The patient will not know which intervention is in each group, so the study will be single-blind. The syringe packaging for both products will be the same.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Working Group/Ethics Committee in Research Faculty of Medicine - Tehran University of Medical Scienc
Street address
Elkhebal St., Quds St., Porsina St., Faculty of Medicine
City
Tehran
Province
Tehran
Postal code
1461884513
Approval date

2025-04-13, 1404/01/24
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1404.043

Health conditions studied

1

Description of health condition studied

Eye rejuvenation

ICD-10 code

L90.9

ICD-10 code description

Atrophic disorder of skin

Primary outcomes

1

Description

The amount of wrinkles

Timepoint

Before and 3 months after the intervention

Method of measurement

Visio face

Secondary outcomes

1

Description

Satisfaction rate

Timepoint

After completing the intervention

Method of measurement

Comparison of the reduction in wrinkles around the eyes of patients after treatment compared to before by the patient herself (score 0 - 10)(feminine)

2

Description

Inflammation

Timepoint

Half an hour after the end of the intervention

Method of measurement

Visit

3

Description

Intensity of pain

Timepoint

At the time of the intervention

Method of measurement

Questionnaire and visit (Score 0 to 10 for pain level)

Intervention groups

1

Description

Control group: Patients are injected with 2 cc of Stromal Vascular Fraction on one side of the eye area in one session.

Category

Treatment - Other

2

Description

Intervention group: Patients undergo injections of 1 cc of Stromal Vascular Fraction and 1 cc of non-cross-linked hyaluronic acid on one side of the eye area in one session.

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

Mohammad Ali Nilforoushzadeh

Street address

No 4, Maryam Alley, South Kamraniyeh Street

City

Tehran

Province

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1937957511

Phone

+98 21 2665 7438

Email

Dr_nilforoush@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ramin Kordi

Street address

Vice President for Research and Technology, 6th
Floor, Central University Organization, corner of Qods
Street, Keshavarz Boulevard

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141765383761

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+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

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 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

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Person responsible for updating data**Contact****Name of organization / entity**

Skin and Stem cell Research Center of Tehran
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Full name of responsible person

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researcher

Latest degree

Ph.D.

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

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