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
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No 4, Maryam Alley, South Kamraniyeh Street
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1937957511
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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
Phone
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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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Person responsible for scientific inquiries

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Mohammad Ali Nilforoushzadeh
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Professor
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Subspecialist

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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