

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of adipose tissue-derived stromal vascular fraction cells (SVF) and nanofat for the maintenance and improvement of autologous fibroblast function in facial rejuvenation

Protocol summary

Study aim

Evaluation of the effect of adipose tissue-derived stromal vascular fraction cells (SVF) and nanofat for the maintenance and improvement of autologous fibroblast function in facial rejuvenation

Design

Clinical trial with a control group and an intervention group, with parallel groups, systematic randomization, one sided blind, phase 1 on 10 patients with Mild to moderate wrinkles

Settings and conduct

This project is carried out in the Skin and Stem Cell Research Center of Tehran University of Medical Sciences. One group is treated with nanofat and SVF cells and autologous fibroblasts by injection, and the other group is treated with nanofat and autologous fibroblasts by injection.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20-60; Having Mild to moderate wrinkles on the face. Exclusion criteria: Pregnancy and breastfeeding; Active infection in face; Using any injectable fillers on the face in the last six months

Intervention groups

Intervention group: They receive 5 cc of nanofat product along with 10 million fibroblast cells and 10 million autologous SVF cells. Control group: They receive 5 cc of nanofat product along with 10 million autologous fibroblast cells.

Main outcome variables

The amount of wrinkles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N30**

Registration date: **2023-05-09, 1402/02/19**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-09, 1402/02/19**

Update count: **0**

Registration date

2023-05-09, 1402/02/19

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

2023-05-05, 1402/02/15

Expected recruitment end date

2023-07-11, 1402/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of adipose tissue-derived stromal

vascular fraction cells (SVF) and nanofat for the maintenance and improvement of autologous fibroblast function in facial rejuvenation		Tehran University of Medical Sciences, Keshavarz blvd	
Public title Evaluation of the effect of SVF cells and nanofat for autologous fibroblast function in facial rejuvenation Purpose Treatment Inclusion/Exclusion criteria Inclusion criteria: Age between 20-60 Having middle to moderate wrinkles Exclusion criteria: Pregnancy and breastfeeding History of cancer Patients with a new history of gel and Botox injections People with Mental Disorders Active infection in the face Age From 20 years old to 60 years old Gender Both Phase 1 Groups that have been masked Data analyser Sample size Target sample size: 10 Randomization (investigator's opinion) Randomized Randomization description Considering that the number of cases in this research plan is 10 people, and both sides of the face are randomly divided into two parts, therefore, the randomization method in this research plan will be done in such a way that the faces of the patients will be randomly selected using systematic randomization method and The numbers generated by the computer will be divided into two groups. Blinding (investigator's opinion) Single blinded Blinding description The data analyst will not be given information about the grouping and will be named A and B groups. Placebo Not used Assignment Parallel Other design features Secondary Ids empty Ethics committees 1 Ethics committee Name of ethics committee Research Ethics Committee of Tehran University of Medical Sciences Street address		City Tehran Province Tehran Postal code 1937957511 Approval date 2022-11-26, 1401/09/05 Ethics committee reference number IR.TUMS.MEDICINE.REC.1401.609	
		Health conditions studied 1 Description of health condition studied Skin aging ICD-10 code L90.9 ICD-10 code description Atrophic disorder of skin	
		Primary outcomes 1 Description The amount of wrinkles Timepoint Before treatment and six month after the last session Method of measurement Visio face	
		Secondary outcomes 1 Description Inflammation Timepoint After each session Method of measurement Questionnaire and visit 2 Description Intensity of pain Timepoint Treatment time Method of measurement Questionnaire and visit	
		Intervention groups 1 Description Intervention group: They receive 5 cc of nanofat product along with 10 million fibroblast cells and 10 million	

autologous SVF cells.

Category

Treatment - Other

2

Description

Control group: They receive 5 cc of nanofat product along with 10 million autologous fibroblast cells.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Skin and Stem Cell Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Street address

No. 4, Maryam Alley, South Kamraniye St.

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Tehran

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1937957511

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Email

Dr_nilforoush@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotuhi

Street address

Floor 6th vice president of research and technology,
Central University Organization, Corner of Qods St.,
Keshavarz Blvd.

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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, 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

Contact

Name of organization / entity

Skin and Stem Cell Research Center, 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, Tehran
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Full name of responsible person
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Position
researcher
Latest degree
Ph.D.
Other areas of specialty/work
Cellular and Molecular Biology
Street address
No. 4, Maryam Alley, South Kamraniye St.
City
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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable