

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation efficiency of autologous Stromal Vascular Fraction (SVF) (Adiposin) transplantation in facial wrinkles

Protocol summary

Study aim

Efficacy assessment of Stromal Vascular Fraction (SVF) cells in facial wrinkle is the aim of this study

Design

In this research, 46 eligible candidate referring to facial wrinkle were chosen purposefully and a code was allocated to each one of them. Biometric parameters of candidate face before intervention would be measured and then suspension of Stromal Vascular Fraction (SVF) cells would be injected in candidate facial wrinkle. A before and after study (without control) design was used.

Settings and conduct

Firstly biometric parameters of candidate face before intervention would be measured and then about 100cc of abdominal fat would be taken via liposuction technique being suspended and finally the suspension of adipose derived stem cells as in Stromal Vascular Fractioned(SVF) would be injected in patient facial wrinkle. After 1,3,6 month from injection, biometric parameters will be assessed for second time to estimate healing rate.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age about 35 to 65 years old, Having no anatomic disorder in face, Wrinkle type between grade 2 to 4, Normal mental health, Ability to comply with the study requirements, Provide written informed consent and comply with the study requirements, Negative pregnancy test (Females)/ Exclusion criteria: being smokers or drinkers any past skin intervention in face, Having many wrinkles on the face type of 1 or 5 of wrinkle scoring, having a mental disorder, Previous treatment with the sponsor's product, History of active autoimmune disease or organ transplantation, Diagnosis of cancer, unless successfully treated or in remission (basal cell carcinoma is excluded), Active or chronic skin disease, Known genetic disorders affecting fibroblasts or collagen, Active systemic infection Requires chronic antibiotic or steroidal therapy, Use of certain commercial

products/procedures to the treatment area prior to study enrollment or plans for use during the study Known allergic reactions to agents used in preparation of treatment, Excessive exposure to sun without adequate sun protection, Use of systemic agents that increase bleeding or clotting, or disorders equated with these effects

Intervention groups

Cell suspension of Stromal Vascular Fraction cells would be injected in candidate facial wrinkle

Main outcome variables

Rejuvenation and facial wrinkle therapy with autologous Stromal Vascular Fraction (SVF) injection

General information

Reason for update

Acronym

Stromal Vascular Fraction (SVF)

IRCT registration information

IRCT registration number: **IRCT20141007019432N2**

Registration date: **2018-01-11, 1396/10/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-11, 1396/10/21**

Update count: **0**

Registration date

2018-01-11, 1396/10/21

Registrant information

Name

Mohammad Amir Amirkhani

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 2220 1710

Email address

amirkhani@health.gov.ir

Recruitment status

Recruitment complete

Funding source**Expected recruitment start date**

2017-12-22, 1396/10/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation efficiency of autologous Stromal Vascular Fraction (SVF) (Adiposin) transplantation in facial wrinkles

Public title

Efficacy assessment of cell therapy in skin aging

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

age about 35 to 65 years old Having no anatomic disorder in face Wrinkle type between grade 2 to 4 Normal mental health Ability to comply with the study requirements Provide written informed consent and comply with the study requirements Negative pregnancy test (Females)

Exclusion criteria:

being smokers or drinkers any past skin intervention in face Having many wrinkles on the face type of 1 or 5 of wrinkle scoring having a mental disorder Previous treatment with the sponsor's product History of active autoimmune disease or organ transplantation Diagnosis of cancer, unless successfully treated or in remission (basal cell carcinoma is excluded) Active or chronic skin disease Known genetic disorders affecting fibroblasts or collagen Active systemic infection Requires chronic antibiotic or steroidal therapy Use of certain commercial products/procedures to the treatment area prior to study enrollment or plans for use during the study Known allergic reactions to agents used in preparation of treatment Excessive exposure to sun without adequate sun protection Use of systemic agents that increase bleeding or clotting, or disorders equated with these effects

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

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, Cross Qods st, Keshavarz Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-11-29, 1396/09/08

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4110

Health conditions studied**1****Description of health condition studied**

Atrophic disorders of skin (aging)

ICD-10 code

Z68.53

ICD-10 code description

Atrophic disorder of skin

Primary outcomes**1****Description**

Quantity of facial wrinkle - Extension

Timepoint

1- 3 - 6 Month after cell therapy

Method of measurement

Biometry with visioface & skin sonography

2

Description

Quality of facial wrinkle - deep

Timepoint

1 - 3 - 6 Month after intervention

Method of measurement

Biometry with visioface & skin sonography

Secondary outcomes

1

Description

Color

Timepoint

1 - 3 - 6 Month after cell therapy

Method of measurement

Biometry with colorimeter

2

Description

Elasticity

Timepoint

1 - 3 - 6 Month after cell therapy

Method of measurement

MPA 9

Intervention groups

1

Description

Firstly biometric parameters of candidate face before intervention would be measured and then about 100cc of abdominal fat would be taken via liposuction technique being suspended and finally the suspension of adipose derived stem cells as in Stromal Vascular Fractioned(SVF) would be injected in patient facial wrinkle.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin & Stem Cell Research Center of Tehran University and Medical Sciences

Full name of responsible person

Mohammad Amir Amirkhani

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Skin & Stem Cell Research Center, Maryam aley, South kamraneye, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Tehran University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Sinacell Corporation

Full name of responsible person

Hoda Hadavandi

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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
Sinacell Corporation
Proportion provided by this source
50
Public or private sector
Private
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
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Position
P.hD Candidate in Cell Therapy
Latest degree
Specialist
Other areas of specialty/work
Others
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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

No - There is not a plan to make this available