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
Mohhammadmir 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
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

Blinding (investigator's opinion)
Not blinded

Blinding description
Not used

Placebo
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
Elastisity
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
Street address
Skin & Stem Cell Research Center, Maryam aley, South kamraneye, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1937957511
Phone
+98 21 2220 1710
Email
Amirkhani2000@yahoo.com

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Niforoushazadeh
Street address
Skin & Stem Cell Research Center, Maryam aley, South kamraneye, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1937957511
Phone
+98 21 2220 1710
Email
mahsamollapur@yahoo.com
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
Street address
Pardis Technology Campus, 16th Innovation Avenue
City
Tehran
Province
Tehran
Postal code
1586877419
Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mahsa Mollapour
Position
P.hD Candidate in Cell Therapy
Latest degree
Specialist
Other areas of specialty/work
Others
Street address
Skin & Stem Cell Research Center, Maryam aley, South kamraneye, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1937957511
Phone
+98 21 2220 1710
Email
dr_nilforoush@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammadali Nilforoushzade
Position
Chife of Center / Dermatologist
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Skin & Stem Cell Research Center, Maryam aley, South kamraneye, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1937957511
Phone
+98 21 2220 1710
Fax
+98 21 2220 1710
Email
dr_nilforoush@yahoo.com
Web page address

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

Data Dictionary
No - There is not a plan to make this available