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 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 Khani

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
Personal information:

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

Placebo
Not used

Assignment
Single

Secondary IDs
empty

Ethics committees

1

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
Quality of facial wrinkle - deep

1 - 3 - 6 Month after intervention

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
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1

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Grant name
Grant code / Reference number
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
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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
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