Evaluation of the efficacy of Stromal Vascular Fraction (SVF) cells on the effect of subcision method in the treatment of acne scars; A one-blind clinical trial

Protocol summary

Study aim
Evaluation the effect of adipose derived Stromal Vascular Fraction (SVF) cells on healing of scar after subcision

Design
This pilot study on 10 patients with moderate and severe acne scarring done. After receiving adequate anesthetic, the scars of the patients are treated with subcision on both sides of the face. Immediately after subsection, one side of the patient's face (intervention group) is injected with adipose tissue-derived SVF cells, and the other side of the face (control group) is injected with nothing on the scar site. All patients are photographed by digital camera before and after treatment. To determine the rate of improvement and compare two sides of the face at the end, patient photographs are reviewed by two blind dermatologist. Patient satisfaction is also recorded and the results are compared.

Settings and conduct
This design is done at the skin and stem cell research center of Tehran university of medical sciences and without the patient's knowledge, after the subcision, SVF cells are injected on one side of the face and nothing is injected on the other side of the scar area.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 20-50; Developing middle to severe atrophic scars in face region. Exclusion criteria: Pregnancy and breastfeeding; Active infection in face; Using any local drugs on face except sun protection creams in last month

Intervention groups
First intervention group: One side of the face is treated with subcision and adipose derived SVF cells in the injection position. Second intervention group: The other side of the face is treated as a control group with subcision.

Main outcome variables
scar's surface; side effects; patient's satisfaction

General information

Reason for update
Acronym

IRCT registration information
IRCT registration number: IRCT20200127046282N4
Registration date: 2021-06-17, 1400/03/27
Registration timing: retrospective

Last update: 2021-06-17, 1400/03/27
Update count: 0

Registration date
2021-06-17, 1400/03/27

Registrant information
Name
Sona Zare
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2221 5558
Email address
sonazarebio@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-15, 1399/11/27

Expected recruitment end date
2021-05-17, 1400/02/27

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty
Scientific title
Evaluation of the efficacy of Stromal Vascular Fraction (SVF) cells on the effect of subcision method in the treatment of acne scars; A one-blind clinical trial

Public title
Evaluation the efficacy of adipose derived SVF cells in the treatment of acne scars

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20-50 Having middle to severe atrophic scar in face region
Exclusion criteria:
Pregnancy and breastfeeding History of cancer Patients with active acne People with Mental Disorders Active infection in the face

Age
From 20 years old to 50 years old

Gender
Both

Phase
1

Groups that have been masked
- Outcome assessor

Sample size
Target sample size: 10

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinding: Patients and physicians will not know the type of treatment, but the evaluator will know the type of patient treatment. Therefore, the study will be conducted blindly.

Placebo
Not used

Assignment
Parallel

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, Keshavarz blvd.
City
Tehran

Province
Tehran
Postal code
1937957511

Approval date
2021-02-14, 1399/11/26

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.1136

Health conditions studied
1

Description of health condition studied
atrophic scar

ICD-10 code
L90.5

ICD-10 code description
Scar conditions and fibrosis of skin

Primary outcomes
1

Description
Scar size

Timepoint
before and 3 month after the intervention

Method of measurement
visio face

2

Description
Side effects

Timepoint
One week after treatment

Method of measurement
Questionnaire and visit

3

Description
Patient Satisfaction

Timepoint
Three and six months after treatment

Method of measurement
Questionnaire

Secondary outcomes
empty

Intervention groups
1

Description
Control group: (Other side of face) After sufficient anesthesia, treatment with subcision.

Category
Treatment - Other
Description
Intervention group: One side of the face after being anesthetized, is first treated with subcision, and then adipose derived Stromal Vascular Fraction (SVF) cells is injected in the scars.

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
Masoumeh Roohaninasab

Street address
No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran

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Sponsors / Funding sources

1
Sponsor

Name of organization / entity
Tehran University of Medical Sciences

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

Contact

Name of organization / entity
Skin and Stem cell Research Center of Tehran University of Medical Sciences

Full name of responsible person
Masoumeh Roohaninasab

Position
assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Title of funding source

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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Title of funding source

Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
assistant Professor

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Specialist

Other areas of specialty/work
Dermatology

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Title of funding source
Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Sona Zare
Position
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Latest degree
Ph.D.
Other areas of specialty/work
cellular and molecular biology
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No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran
City
Tehran
Province

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