Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Title : Evaluation of clinical improvement of wrinkles in the whole facial skin using radiofrequency microneedling with adipose derived stem cell-conditioned medium

Protocol summary

Study aim

Evaluation the effect of conditioned media of adipose derived stem cells on repair of face wrinkles after micro needling

Design

This pilot study on 10 patients with moderate wrinkles done. At each session, after receiving adequate anesthetic, the wrinkles of the patients are treated with micro needling on both sides of the face. In each session immediately after the micro needling, one side of the patient's face, the conditioned media of ADSC, and the other side of the face, the physiologic serum was applied locally to the wrinkles area for one hour. This procedure is repeated 4 times at intervals of 4 weeks. 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 micro needling, one side of the face of conditioned media of ADSC and other side for blinding is used of the physiology serum in the wrinkles.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20-60; Having 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

First intervention group: One side of the face is treated with micro needling and conditioned media of adipose derived stem cells in the topical position. Second intervention group: The other side of the face is treated as a control group with micro needling and physiologic serum.

Main outcome variables

The amount of wrinkles; side effects; patient's satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N3**
Registration date: **2021-06-06, 1400/03/16**
Registration timing: **prospective**

Last update: **2021-06-06, 1400/03/16**
Update count: **0**

Registration date

2021-06-06, 1400/03/16

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)
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+98 21 2665 7438
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-21, 1400/04/30

Expected recruitment end date
2022-03-20, 1400/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Title : Evaluation of clinical improvement of wrinkles in the whole facial skin using radiofrequency microneedling with adipose derived stem cell-conditioned medium

Public title
Evaluation of clinical improvement of conditioned media of adipose derived stem cells in the treatment of wrinkles in the whole facial skin
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20-60 Having middle wrinkles in face region
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

- Participant
- Data analyser

Sample size
Target sample size: **10**
More than 1 sample in each individual
Number of samples in each individual: **2**
A half face will be considered as the control group and one half as an intervention group.
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
In each session, immediately after the micro needling on one side of the face, the conditioned media of adipose derived stem cells and the other side of the face saline solution is used topically on the wrinkles.
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
Keshavarz blvd, Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1937957511
Approval date
2020-11-14, 1399/08/24
Ethics committee reference number
IR.TUMS.VCR.REC.1399.601

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 one month after the last session
Method of measurement
Visio face

Secondary outcomes

1

Description
side effects
Timepoint
One week after session
Method of measurement
Questionnaire and visit

Intervention groups

1

Description
Control group: (Other side of face) After sufficient anesthesia, first treatment with micro needling, and then physiological serum is applied topically to the site of the wrinkles for one hour. This procedure is repeated 4 times with intervals of 4 weeks. .

Category
Treatment - Other

2

Description
Intervention group: One side of the face after being anesthetized, is first treated with micro needling, and then adipose conditioned media of adipose derived stem cells is applied topically to the wrinkles for one hour. This procedure is repeated 4 times with intervals of 4 weeks.

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
Mohammad Ali Nilforoushzadeh

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

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Sponsors / Funding sources

1

Sponsor

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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
Skin and Stem cell Research Center of 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 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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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable