

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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)

Phone

+98 21 2665 7438

Email address

sonazarebio@gmail.com

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

Street address

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Skin and Stem cell Research Center of 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

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

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Ali Nilforoushzadeh

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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researcher

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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