

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Evaluation the effect of adipose derived stem cells conditioned medium (ADSC-CM) on rejuvenation after resurfacing with ablative fractional carbon dioxide laser

#### Protocol summary

##### Study aim

Evaluation the effect of adipose derived stem cells conditioned medium (ADSC-CM) on rejuvenation after resurfacing with ablative fractional carbon dioxide laser

##### Design

Clinical trial with a control group and an intervention group, with parallel groups, double-blind, randomized based on random number table, phase 1 on 10 patients with moderate and severe wrinkles

##### Settings and conduct

This project is carried out in the Dermatology and Stem Cell Research Center of Tehran University of Medical Sciences. One group is treated with laser and adipose derived stem cells conditioned medium topically and the other group is treated with laser and PRP topically.

##### 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

Intervention group: A group treated with laser and adipose derived stem cells conditioned medium is placed topically. Control group: The other group is treated with laser and PRP topically.

##### Main outcome variables

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

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200127046282N19**

Registration date: **2022-06-06, 1401/03/16**

Registration timing: **prospective**

Last update: **2022-06-06, 1401/03/16**

Update count: **0**

##### Registration date

2022-06-06, 1401/03/16

##### 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

2022-06-20, 1401/03/30

##### Expected recruitment end date

2022-09-21, 1401/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the effect of adipose derived stem cells conditioned medium (ADSC-CM) on rejuvenation after resurfacing with ablative fractional carbon dioxide laser

##### Public title

Evaluation of clinical improvement of conditioned media

of adipose derived stem cells in the treatment of wrinkles in the 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

- Outcome assessor
- Data analyser

## Sample size

Target sample size: **20**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In each session, immediately after fractional laser, adipose-derived stem cells conditioned medium are used in one group and PRP is used in the other group after laser.

## 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

2022-02-21, 1400/12/02

## Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1412

## 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 six month after the last session

#### Method of measurement

Visio face

## Secondary outcomes

### 1

#### Description

Inflammation

#### Timepoint

After each session

#### Method of measurement

Questionnaire and visit

### 2

#### Description

Intensity of pain

#### Timepoint

Treatment time

#### Method of measurement

Questionnaire and visit

## Intervention groups

### 1

#### Description

Intervention group: After adequate anesthesia, a group is first treated with laser and then the stem cells conditioned medium is applied topically to the wrinkle site for one hour. This method is repeated 3 times with 4 week intervals.

#### Category

Treatment - Other

## 2

### Description

Control group: After adequate anesthesia, a group is first treated with laser and then the PRP is applied topically to the wrinkle site for one hour. This method is repeated 3 times with 4 week intervals.

### 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

##### City

Tehran

##### Province

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##### Postal code

1937957511

##### Phone

+98 21 2665 7438

##### Email

Dr\_nilforoush@yahoo.com

## 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

Mohammad Ali Nilforoushzadeh

##### Street address

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

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Dr\_nilforoush@yahoo.com

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

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Skin and Stem cell Research Center of Tehran University of Medical Sciences

##### 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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## 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