

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Transplantation of autologous skin fibroblast cells for treatment of nasolabial wrinkles

#### Protocol summary

##### Summary

The purpose of the study is to evaluate the efficacy of skin fibroblasts in the treatment of lesions related to the skin aging. The volunteer's number is referring to the center of skin and stem cell research with a moderate wrinkle (degree of 3 and 4 Glogue scale) contains 16 people. At first, the biometric parameters in patients face should be estimated before intervention, then a biopsy will be taken from back region of the patients ear and the dermal fibroblast cells will be isolated, cultured and proliferated for three times. Each time, 10 million cells will be injected on each side of nasolabial fold for three times within 2 weeks intervals. After 1, 3 and 6 months from intervention, Patients will be checked in order of biometric parameters and their information will be recorded and analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201506271159N17**

Registration date: **2017-09-15, 1396/06/24**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-09-15, 1396/06/24

##### Registrant information

###### Name

Mohamad Ali Nilforoushzadeh

###### Name of organization / entity

Skin and Stem Cell Research Center, Tehran  
University of Medical sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2220 5158

##### Email address

sdllrc@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

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

##### Expected recruitment start date

2016-10-06, 1395/07/15

##### Expected recruitment end date

2017-10-07, 1396/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Transplantation of autologous skin fibroblast cells for treatment of nasolabial wrinkles

##### Public title

Efficacy assessment of cell therapy with autologous fibroblast in skin aging

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age about 35 to 55 years old;- Patients with mild to moderate wrinkles according to Glogue scale I-III; No coagulation disorders and use of anti coagulated drugs; No infection in treated site; No fever able diseases; No chronic liver diseases; No pregnancy or breast-feeding; Having no anatomic disorder in face; Normal mental health; Having a good cooperation with research team. 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; having an obsessed disorder;  
having any skin disorder; having any major disorder;  
having a systemic disorder; having an oral disorder;

#### Age

From **35 years** old to **55 years** old

#### Gender

Both

#### Phase

1-2

#### Groups that have been masked

No information

#### Sample size

Target sample size: **16**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical sciences

##### Street address

Tehran University of Medical Sciences, Cross Qods st,  
Keshavarz Blvd, Tehran, Iran

##### City

Tehran

##### Postal code

#### Approval date

2014-09-29, 1393/07/07

#### Ethics committee reference number

1502/130/93/ص

## Health conditions studied

### 1

#### Description of health condition studied

Face wrinkles

#### ICD-10 code

L98.8

#### ICD-10 code description

Other specified disorders of skin and subcutaneous  
tissue

## Primary outcomes

### 1

#### Description

Severity of face wrinkles

#### Timepoint

1- 3 - 6 Month after cell therapy

#### Method of measurement

Biometry with visioface & skin sonography

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First of all, fibroblast cells are isolated from biopsy of  
back region of patient's ear, then ten million cells will be  
injected on each side of nasolabial fold for three times  
within 2 weeks interval. At the end, the rate of nasolabial  
fold improvement is estimated.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Skin and Stem Cell Research Center of Tehran  
University of Medical sciences

##### Full name of responsible person

Dr Mohammad Ali Nilforoushzadeh

##### Street address

Skin and Stemcell Research Center, Maryam aley,  
South kamraneye, Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Skin and Stem Cell Research Center, Maryam aley,  
South kamraneye, Tehran, Iran

##### Full name of responsible person

Dr Mohammad Ali Nilforoushzadeh

##### Street address

Skin and Stemcell Research Center, Maryam aley,  
South kamraneye, Tehran, Iran

##### City

Tehran

#### 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, Maryam aley, South kamraneye, Tehran, Iran

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

empty

**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**

PhD/Laboratory manager

**Other areas of specialty/work****Street address**

Skin and Stem Cell Research Center, Maryam aley,  
South kamraneye, Tehran, Iran

**City**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2220 1710

**Fax****Email**

sonazarebio@gmail.com

**Web page address****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**

Dr. Mohammadali Nilforoushzade

**Position**

Chife of Center / Dermatologist

**Other areas of specialty/work****Street address**

Skin and Stem Cell Research Center, Maryam aley,  
South kamraneye, Tehran, Iran

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dr\_nilforoush@yahoo.com

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

Skin and Stem Cell Research Center of Tehran  
University of Medical Science

**Full name of responsible person**

Sona Zare

**Position**

PhD/ Laboratory manager

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

**Study Protocol**

empty

**Statistical Analysis Plan**

empty

**Informed Consent Form**

empty

**Clinical Study Report**

empty

**Analytic Code**

empty

**Data Dictionary**

empty