

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

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City

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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, 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,
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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Chife of Center / Dermatologist

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Full name of responsible person

Sona Zare

Position

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

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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