

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy assessment of adipose drive stem cell in nasolabial fold wrinkles

Protocol summary

Summary

Efficacy assessment of adipose driven stem cells in nasolabial fold wrinkle is the aim of this study. Firstly biometric parameters of patient face before intervention would be measured and then about 100cc of abdominal fat would be taken via liposuction technique being suspended and finally the suspension of adipose derived stem cells as in Stromal Vascular Fractioned(SVF) would be injected in patient nasolabial fold. After 1,3,6 month from injection, biometric parameters will be assessed for second time to estimate healing rate. Inclusion criteria are as to have 35 to 55 years old, no systemic disease, have nasolabial wrinkle type 2,3,4. Exclusion criteria are to have many or huge wrinkles and to be under any intervention in face before as gel injection and etc. Study Population group is from people referring to skin and stem cell research center and sample size is 16 person. our intervention is injection of adipose derived stem cells in nasolabial fold and to compare wrinkle rate after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100719432N1**

Registration date: **2015-05-31, 1394/03/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-31, 1394/03/10

Registrant information

Name

Mohammad Amir Khani

Name of organization / entity

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

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2014-12-21, 1393/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy assessment of adipose drive stem cell in nasolabial fold wrinkles

Public title

Efficacy assessment of cell therapy in skin aging

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age about 35 to 55 years old; Having no anatomic disorder in face; Wrinkle type between grade 2 to 4; 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

3

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

2014-09-07, 1393/06/16

Ethics committee reference number

130/1254/ص

Health conditions studied

1

Description of health condition studied

atrophic disorders of skin (aging)

ICD-10 code

L90.9

ICD-10 code description

Atrophic disorder of skin, unspecified

Primary outcomes

1

Description

Quantity of nasolabial fold wrinkle - Extension

Timepoint

1- 3 - 6 Month after cell therapy

Method of measurement

Biometry with visioface & skin sonography

2

Description

Quality of nasolabial fold wrinkle - deep

Timepoint

1 - 3 - 6 Mounth after intervention

Method of measurement

Visio face & skin sono

Secondary outcomes

1

Description

Color

Timepoint

1 - 3 - 6 Month after cell therapy

Method of measurement

Biometry with colorimeter

2

Description

Elastisity

Timepoint

1 - 3 - 6 Eounth after intervention

Method of measurement

MPA 9

Intervention groups

1

Description

2cc suspension of adipose drive stem cell (SVF) that made from 100 cc abdominal adipose will injected in nasolabial fold and the end, healing rate of nasolabial fold wrinkle will measured.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

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

Full name of responsible person

Dr Amirkhani PhD Condidate of center

Street address

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

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Nilforoushzade

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

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Grant name

ردیف متمرکز مرکز پوست

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

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 & Stem Cell Research Center of Tehran
University of Medical sciences

Full name of responsible person

Dr. Mohammadmir Amirkhani

Position

Project Manager - Medical Doctor

Other areas of specialty/work

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Other areas of specialty/work

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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