

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation efficiency of autologous fibroblast (Cell fibrosin) transplantation in facial wrinkles

Protocol summary

Study aim

Efficacy assessment of fibroblast cells in facial wrinkle is the aim of this study

Design

In this research, 46 eligible candidate referring to facial wrinkle were chosen purposefully and a code was allocated to each one of them. Biometric parameters of candidate face before intervention would be measured and then suspension of fibroblast cells would be injected in candidate facial wrinkle.

Settings and conduct

Firstly biometric parameters of candidate face before intervention would be measured and then about 0.5 cm² of skin biopsy from behind the ear would be taken via puncher. Fibroblast cells isolated and cultured in laboratory. Cell suspension of fibroblast cells would be injected in candidate facial wrinkle. After 1,3,6 month from injection, biometric parameters will be assessed for second time to estimate healing rate.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age about 35 to 65 years old; having no anatomic disorder in face; wrinkle type between grade 2 to 4; normal mental health; ability to comply with the study requirements; provide written informed consent and comply with the study requirements; negative pregnancy test (females). 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; previous treatment with the sponsor's product; history of active autoimmune disease or organ transplantation; diagnosis of cancer; unless successfully treated or in remission (basal cell carcinoma is excluded); active or chronic skin disease; known genetic disorders affecting fibroblasts or collagen; active systemic infection requires chronic antibiotic or steroidal therapy; use of certain commercial products/procedures to the treatment area prior to study enrollment or plans for use during the study Known allergic reactions to agents used in preparation of

treatment, Excessive exposure to sun without adequate sun protection; use of systemic agents that increase bleeding or clotting, or disorders equated with these effects.

Intervention groups

Cell suspension of fibroblast cells would be injected in candidate facial wrinkle

Main outcome variables

Rejuvenation and facial wrinkle therapy with autologous fibroblast injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141007019432N3**

Registration date: **2018-01-12, 1396/10/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-12, 1396/10/22**

Update count: **0**

Registration date

2018-01-12, 1396/10/22

Registrant information

Name

Mohammad Amir Amirkhani

Name of organization / entity

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

Country

Iran (Islamic Republic of)

Phone

+98 21 2220 1710

Email address

amirkhani@health.gov.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation efficiency of autologous fibroblast (Cell fibrosin) transplantation in facial wrinkles

Public title

Efficacy assessment of cell therapy in skin aging

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

age about 35 to 65 years old Having no anatomic disorder in face Wrinkle type between grade 2 to 4 Normal mental health Ability to comply with the study requirements Provide written informed consent Negative pregnancy test (Females)

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 Previous treatment with the filler's product History of active autoimmune disease or organ transplantation Diagnosis of cancer, unless successfully treated or in remission (basal cell carcinoma is excluded) Active or chronic skin disease Known genetic disorders affecting fibroblasts or collagen Active systemic infection Requires chronic antibiotic or steroidal therapy Known allergic reactions to agents used in preparation of treatment Excessive exposure to sun without adequate sun protection Use of systemic agents that increase bleeding or clotting, or disorders equated with these effects

AgeFrom **35 years** old to **65 years** old**Gender**

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **46****Randomization (investigator's opinion)**

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

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

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-11-25, 1396/09/04

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4094

Health conditions studied**1****Description of health condition studied**

Atrophic disorders of skin (aging)

ICD-10 code

Z68.53

ICD-10 code description

Atrophic disorder of skin

Primary outcomes**1****Description**

Quantity of facial wrinkle - Extension

Timepoint

Months: 1, 3 and 6 after cell therapy

Method of measurement

Biometry with visioface & skin sonography

2**Description**

Quality of facial wrinkle - deep

Timepoint

Months: 1, 3 and 6 after cell therapy

Method of measurement

Biometry with visioface & skin sonography

Secondary outcomes

1

Description

Color

Timepoint

Months: 1, 3 and 6 after cell therapy

Method of measurement

Biometry with colorimeter

2

Description

Elastisity

Timepoint

Months: 1, 3 and 6 after cell therapy

Method of measurement

MPA 9

Intervention groups

1

Description

Firstly biometric parameters of candidate face before intervention would be measured and then about 0.5 cm² of skin biopsy from behind the ear would be taken via puncher. Fibroblast cells isolated and cultured in laboratory. Cell suspension of fibroblast cells would be injected in candidate facial wrinkle. After 1,3,6 month from injection, biometric parameters will be assessed for second time to estimate healing rate.

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

Mohammad Amir Amirkhani

Street address

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

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2220 1710

Email

Amirkhani2000@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Nilforoushzadhe

Street address

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

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2220 1710

Email

mahsamollapur@yahoo.com

Grant name

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

50

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

2

Sponsor

Name of organization / entity

Sinacell Corporation

Full name of responsible person

Hoda Hadavandi

Street address

Pardis Technology Campus, 16th Innovation Avenue

City

Tehran

Province

Tehran

Postal code

1586877419

Phone

+98 21 7625 0664

Email

mahsamollapur@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sinacell Corporation

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

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

Academic

Province

Tehran

Postal code

1937957511

Phone

+98 21 2220 1710

Fax

+98 21 2220 1710

Email

dr_nilforoush@yahoo.com

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

Tehran University of Medical Sciences

Full name of responsible person

Mahsa Mollapour

Position

P.hD Candidate in Cell Therapy

Latest degree

Specialist

Other areas of specialty/work

Cell therapy

Street address

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

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2220 1710

Email

Mahsamollapur@yahoo.com

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

Tehran University of Medical Sciences

Full name of responsible person

Mahsa Mollapour

Position

P.hD Candidate in Cell Therapy

Latest degree

Specialist

Other areas of specialty/work

Others

Street address

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

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2220 1710

Email

Mahsamollapur@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammadali Nilforoushzade

Position

Chife of Center / Dermatologist

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

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

City

Tehran

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

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available