

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Evaluation the efficacy rate of autologous fibroblast transplantation in facial contour deformities

Protocol summary

Summary

Objectives: To evaluate the efficacy, durability and adverse events of autologous fibroblast transplantation in wrinkle and acne scar. Design: open-label, non-randomized phase II, single center clinical trial. Sample size: 60 patients. Participants: Age of at least 18 years old; wrinkle or acne scar score of at-least 2 out 7. Exclusion Criteria: Pregnancy or lactation; filler, botulinum toxin or laser during past 6 months. Primary Outcome: Decrease in wrinkle or scar score. Secondary outcome: Safety of the intervention. Intervention: A small piece of retroauricular site of patient is taken, fibroblasts are isolated and cultured. Cultured fibroblasts are injected into intradermal of treatment sites in 3 sessions and 4 weeks intervals. Patients were followed 2, 6 and 12 months after 3rd injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508201031N15**

Registration date: **2016-08-04, 1395/05/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-04, 1395/05/14

Registrant information

Name

Nasser Aghdami

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2356 2000

Email address

nasser.aghdami@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Department of Regenerative Biomedicine, Cell Science Research Center, Royan Institute for Stem Cell Biology and Technology

Expected recruitment start date

2008-08-21, 1387/05/31

Expected recruitment end date

2010-10-22, 1389/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy rate of autologous fibroblast transplantation in facial contour deformities

Public title

Facial contour deformities

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age>18 years; facial wrinkle or acne scar of at-least 2 out 7; Ability to sign informed consent. Exclusion Criteria: Known allergy or sensitivity to collagen fillers; history of soft tissue augmentation to the area during last 6 months; autologous fat transfer in the last 6 months; facial Kaposi sarcoma; active skin diseases or inflammation of the treatment area; Silicon injection in treatment site; pregnancy or lactating; systemic immunosuppressive or steroid drugs during past 6 months; current anticoagulant therapy; disease of connective tissue; malignant disease; Positive HIV, HBV,

HCV

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
No other features

Secondary Ids

1

Registry name
clinicaltrials.gov

Secondary trial Id
NCT 01115634

Registration date
2010-01-05, 1388/10/15

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Royan infertility institute

Street address
Eastern Hafez St,Northern Banihashem St, 45 m
Resalat highway

City
Tehran

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
012/87/پ

Health conditions studied

1

Description of health condition studied
Acne Scar

ICD-10 code
L90.5

ICD-10 code description
Scar conditions and fibrosis of skin

2

Description of health condition studied
Wrinkle

ICD-10 code
L98.9

ICD-10 code description
Disorder of skin and subcutaneous tissue, unspecified

Primary outcomes

1

Description
Decrease in scar and wrinkle score

Timepoint
2, 6 and 12 months after cell injection

Method of measurement
Based on evaluator assessment score according to
standardized 7-point grading

Secondary outcomes

1

Description
Safety

Timepoint
2, 6 and 12 months after cell injection

Method of measurement
Assessments based on evaluator and subject

Intervention groups

1

Description
3 sessions of intradermal injection of autologous cultured
fibroblast 0.1 ml along each cm with 4 weeks intervals

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Skin Clinic of Royan Institute

Full name of responsible person
Hamid Gourabi

Street address
Eastern Hafez St,Northern Banihashem St, 45 m
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City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Hamid Gourabi

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Royan Institute

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

Royan Institute

Full name of responsible person

Amir Bajouri

Position

M.D/ Researcher

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Royan cell Therapy Center

Full name of responsible person

Nasser Aghdami

Position

M.D, PhD

Other areas of specialty/work

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Person responsible for updating data

Contact

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Position

Researcher

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