

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparative study of topical TCA %50 and cultured autologous fibroblasts in the treatment of the atrophic scars of face. (Pilot Study)

Protocol summary

Summary

The purpose of this pilot study is to compare efficacy and side effects of injection of living autologous fibroblast versus TCA 50% for the treatment of atrophic facial scar. The study Population consists of patients with facial contour deformities including acne scars or leishmaniasis scar. A total of 20 patients are randomly assigned into two groups. In one group, the patients receive 3 doses of living autologous fibroblast (20 million/ml) at two weeks interval. In another group, the patients receive 3 times treatment of topical TCA 50%. TCA 50% was applied once monthly for 3 months. Efficacy evaluations are performed every 2 weeks until three months and then 6 and 12 months after the first treatment. The size of scar, patient's satisfaction, and side effects are recorded in each visit.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902081159N2**

Registration date: **2010-10-16, 1389/07/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-10-16, 1389/07/24

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

Isfahan University of Medical Sciences

Expected recruitment start date

2010-05-22, 1389/03/01

Expected recruitment end date

2012-02-20, 1390/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of topical TCA %50 and cultured autologous fibroblasts in the treatment of the atrophic scars of face. (Pilot Study)

Public title

Comparative study of topical TCA %50 and cultured autologous fibroblasts in the treatment of the atrophic scars of face.(Pilot Study)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age more than 18 years, dissatisfaction of facial appearance, Negative pregnancy test at the screening visit, signing written informed consent, compliance with the study requirements, Healthy, non-scarred skin for biopsy Exclusion Criteria: Previous treatment with dermal filler or other method, participating in another clinical trial, History of autoimmune disease or organ transplantation, History of cancer, Active systemic infection, need to chronic

antibiotic or steroidal therapy, Using systemic agents that increase bleeding or clotting, any disorder that increase bleeding or clotting, Pregnancy or breast feeding, Known allergic reaction to components of study treatment and/or study injection procedure, Excessive exposure to sun or sunburn in the post-auricular area, Patients with psychological disorders

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezar Jarib Boulevard, Isfahan, Iran

City

Isfahan

Postal code

Approval date

empty

Ethics committee reference number

4/125763

Health conditions studied

1

Description of health condition studied

atrophic scar

ICD-10 code

L90.5

ICD-10 code description

Scar conditions and fibrosis of skin

Primary outcomes

1

Description

Scar size

Timepoint

before and after the intervention

Method of measurement

Photography of scar before beginning of the study and millimeter paper

Secondary outcomes

1

Description

clinical improvement of scar

Timepoint

Before the study and 3, 6, and 12 months after the beginning of study

Method of measurement

Photography of scar at each visit

Intervention groups

1

Description

TCA 50%, topical, once monthly for 3 months.

Category

Treatment - Drugs

2

Description

Autologous fibroblasts (20million/mL), three times with 1-2 weeks intervals

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin Disease and Leishmaniasis Research Center
(Sedigheh Tahereh)

Full name of responsible person

Mohamad Ali Nilforoushzadeh

Street address

Skin Diseases and Leishmaniasis Research Center,
Third Floor, Sedigheh Tahereh Research Centers,
Next to Shahidan Square, Khoram Street, Isfahan,
Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Isfahan University of Medical Sciences

Street address

Hezar Jarib Boulevard, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan 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 Disease and Leishmaniasis Research Center
(Sedigheh Tahereh)

Full name of responsible person

Dr Mohamad Ali Nilforushzade

Position

Associate Professor of Dermatology, fellowship of laser and skin surgery /Head of Skin Disease and Le

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Skin Disease and Leishmaniasis Research Center
(Sedigheh Tahereh)

Full name of responsible person

Dr Mohamad Ali Nilforushzade

Position

Associate Professor of Dermatology, Fellowship of laser and skin surgery/ Head of Skin Disease and L

Other areas of specialty/work

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Skin Diseases and Leishmaniasis Research Center,
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Web page address

Person responsible for updating data

Contact

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