

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigation on Safety and Efficacy of Autologous Human Fibroblasts Transplantation in Regeneration of Atrophic Cutaneous Leishmaniasis Scar.

Protocol summary

Study aim

To study the safety and efficacy of autologous fibroblast transplantation into atrophic scar of cutaneous leishmaniasis.

Design

A pilot study on Safety and Efficacy of Autologous Human Fibroblasts Transplantation in Regeneration of Atrophic Cutaneous Leishmaniasis Scar. Five patients are treated with their autologous dermal fibroblasts. The scars are investigated before and after transplantation.

Settings and conduct

In this pilot study, ear skin biopsies taken from patients at Center of Research and Training in Skin Diseases and Leprosy. The samples are moved to clean room at Iran University of Medical Sciences to isolate fibroblasts. The cells are injected into the lesions 3 times with 2 months intervals and 2, 6, and 12 months follow ups using VisioFace, Sonography and Cotometer.

Participants/Inclusion and exclusion criteria

Inclusion Criteria 1- Ages 15-65 2- Scar lesions caused by Cutaneous leishmaniasis grade 3 to 7 3- The willingness to provide informed consent, the ability to communicate with the investigator during follow ups. Exclusion Criteria 1- Use of Retinoids in the last 6 months 2- Pregnancy 3- Laser therapy in the last 6 months 4- Cancer or any chronic systemic disease 5- Chemical therapy 6- Mesotherapy 7- Active infection to Leishmaniasis 8- Organ or cell transplantation 9- Autoimmune disease 10- Breast feeding 11- Dermal Filler in the last 6 months 12- Plastic surgery at the site of Cutaneous leishmaniasis lesion 13- Use of Corticosteroids 14- Excessive exposure to sun 15- Participation in other clinical trials, using systemic medication or other treatment that might interfere with this study 16- Evidence of infection in the lesion or elsewhere on body.

Intervention groups

- Clinical grade Autologous Fibroblast Transplantation in

the lesions caused by cutaneous leishmaniasis .

Main outcome variables

Dermal Thickness; Scar Diameter; Elasticity; Patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150715023218N1**

Registration date: **2021-02-23, 1399/12/05**

Registration timing: **prospective**

Last update: **2021-02-23, 1399/12/05**

Update count: **0**

Registration date

2021-02-23, 1399/12/05

Registrant information

Name

Faezeh Faghihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4722

Email address

faghihi.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation on Safety and Efficacy of Autologous Human Fibroblasts Transplantation in Regeneration of Atrophic Cutaneous Leishmaniasis Scar.

Public title
Fibroblast in Cutaneous Leishmaniasis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Ages 15-65 Scar lesions caused by Cutaneous leishmaniasis grade 3 to 7; The willingness to provide informed consent for participation in the trial and the ability to communicate with the investigator during follow ups.
Exclusion criteria:
Use of Retinoids in the last 6 months Pregnancy Laser therapy in the last 6 months Cancer or any chronic systemic disease Chemical therapy Mesotherapy Active infection to Leishmaniasis in the scar Organ or cell transplantation Autoimmune disease Breast feeding Dermal Filler in the last 6 months Plastic surgery at the site of Cutaneous leishmaniasis lesion Use of Corticosteroids Excessive exposure to sun. Subjects who are enrolled in any other clinical trial using systemic medication; or any other treatment that might interfere with this study Subjects with evidence of infection on area to be treated or elsewhere on body.

Age
From **15 years** old to **65 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **5**
More than 1 sample in each individual
Number of samples in each individual: **5**
The group treated with Autologous Fibroblast

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

Ethics Committee of Iran University of Medical Sciences

Street address

Cellular and Molecular Research Center, Iran University of Medical Sciences, Hemmat Highway

City

TEHRAN

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2020-05-03, 1399/02/14

Ethics committee reference number

IR.IUMS.REC.1399.196

Health conditions studied

1

Description of health condition studied

Cutaneous Leishmaniasis

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

Primary outcomes

1

Description

Dermal thickness

Timepoint

Before intervention, 2, 6 and 12 months after the third transplantation of Fibroblasts

Method of measurement

Sonography

2

Description

Elasticity

Timepoint

Before intervention, 2, 6 and 12 months after the third transplantation of Fibroblasts

Method of measurement

Cotometer

3

Description

wound Diameter

Timepoint

Before intervention, 2, 6 and 12 months after the third transplantation of Fibroblasts

Method of measurement

visioFace

Secondary outcomes

1

Description

Patients Satisfaction

Timepoint

Before intervention, 2, 6 and 12 months after the third transplantation of Fibroblasts

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Fibroblast Transplantation on number of 5 patients suffered from Cutaneous leishmaniasis to regenerate scar lesions after three subsequent fibroblast injections (20 mil/ turn) with 2 months intervals. scars are evaluated before and after transplantation.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Center of Research and Training in Skin Diseases and Leprosy

Full name of responsible person

Ali Khamesipour

Street address

The Center for Research and Training in Skin Diseases and Leprosy, No. 415, Naderi St., Taleghani Ave., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Grant name

98-4-99-16804

Grant code / Reference number

98-4-99-16804

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Faezeh Faghihi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Tissue Engineering

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Person responsible for scientific inquiries

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Paper- Partly(main measurements)

When the data will become available and for how long

After paper acceptance

To whom data/document is available

Scientists and the health industries

Under which criteria data/document could be used

Formal contact

From where data/document is obtainable

Faezeh Faghihi, Cellular and Molecular Research Center,
Iran University of Medical Sciences, Tehran, Iran. +98 21
86704722

What processes are involved for a request to access data/document

Formal written request- Acceptance of Research
Committee of Cellular and Molecular Research Center at
Iran University of Medical Sciences.

Comments