

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Efficacy of mechanical nanofat injection method in improvement of atrophic scar of cutaneous leishmaniasis in Khorasan Razavi

Protocol summary

Study aim

Treatment effects and possible side effects of nano-fat injection in improvement of atrophic scars due to cutaneous leishmaniasis

Design

Clinical trial without control group, Blinding and randomization have not been done on 14 patient

Settings and conduct

This study will be conducted on 14 patients with facial leishmaniasis scar who will be visiting dermatology clinic in imam reza hospital at first fat will be harvested then via sedimentation method blood and tumescent fluid will be separated from fat, and at last the final product will be injected intradermally using a 1 cc syringe with a 1 cm space between each injection site Patient assessment recovery will be preformed 6 months later

Participants/Inclusion and exclusion criteria

Patients over 18 years of age with leishmaniasis scars on the face; At least two years since the active leishmaniasis infection recovered; Patient consent
Exclusion criteria: Under 18 and over 50 years of age; Mental Illness Bleeding disorders or usage of anticoagulants; Pregnancy and Lactation

Intervention groups

consent will be obtained from patients more than 18 years of age with leishmaniasis facial scar before entering the study Technique: First Fat will be harvested, Then, will be separated from the blood and tumescent solution by sedimentation method, after that nano-fat will be prepared by emulsifying the fat via 2.4, 1.4 and 1.1 size connectors then the final product will be transferred to 1 cc syringes and injected with 30 gauge needles intradermal and at intervals of 1 cm.

Main outcome variables

Change in scar intensity based on it color, depth and consistency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200526047577N1**

Registration date: **2022-02-14, 1400/11/25**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-14, 1400/11/25**

Update count: **0**

Registration date

2022-02-14, 1400/11/25

Registrant information

Name

Mohammed Tehami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3838 3903

Email address

mohd.tehami@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-30, 1400/10/09

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of mechanical nanofat injection method in improvement of atrophic scar of cutaneous leishmaniasis in Khorasan Razavi

Public title

Effect of fat injection in improvement of atrophic scar of cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Atrophic scars due to Leshminiasis Did not seek treatment for the last 6 months Facial scar Leishmaniasis infection improvement for at least two years

Exclusion criteria:

Patients with Bleeding disorders Patient who did not fill a consent form Patient with comorbidities e.g. Diabetes Mellitus, Hyper tension or autoimmune disorders Pregnancy and breastfeeding

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **14**

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 Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Scineces (Ghorashi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2021-12-04, 1400/09/13

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.585

Health conditions studied

1

Description of health condition studied

Cutaneous leishmaniasis scar

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

Primary outcomes

1

Description

Change in scar intensity based on it color and depth and consistency

Timepoint

6 months

Method of measurement

The patient and observer scar assessment scale (POSAS) and Photographs

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients over 18 years of age with leishmaniasis scars on the face

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic, Imam Reza a. Hospital

Full name of responsible person

Mohammed Tehami

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Ibin sina street, Imam Reza a Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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ramresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mohammed Tehami
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

All data can be shared after patient are made unidentified.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author.

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

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments