

# 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

##### Street address

Ibin sina street, Imam Reza a Hospital

##### City

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##### Province

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##### Postal code

9137913316

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mohd.tehami@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Dr. Majeed Ghaior  
**Street address**  
Central Building of Mashhad University of Medical Sciences (Ghorashi), Daneshgah 16, Daneshgah street  
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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

#### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Dr. Vahid Mashayekhi  
**Position**  
Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dermatology  
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## Person responsible for updating data

#### 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**  
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**Postal code**  
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**Phone**  
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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**