

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effectiveness of autologous fat transfer on the quality of burn-induced scars

Protocol summary

Study aim

Analyze the qualitative impact of using autologous fat injection to treat burn scars in comparison to using normal saline to treat scars.

Design

Randomized double blind parallel group controlled clinical trial on 18 patients (36 samples) randomization with sealed envelope

Settings and conduct

Chronic burn patients were referred to Hazrat Fatemeh Hospital and Motahari Hospital in Tehran. Venue: Hazrat Fatemeh Hospital/Motahari Hospital Method: Mark the desired scar for intervention, divide it into two halves and perform the described interventions in the operating room under general anesthesia by a plastic and reconstructive surgery specialist. Randomization: Using a sealed envelope Blinded group: principal investigator, outcome assessor, patient, and health care providers after the intervention compared to the half-intervention or control Unblinded group: surgeon performing the procedure

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patient older than 18 years old 2 - Having a burn scar 3- At least one year has passed since the burn injury Exclusion criteria: 1. Any serious systemic disease that puts the patient at a higher risk for general anesthesia.

Intervention groups

Intervention group: patients with burn scars in the marked half of the scar who receive fat injection intervention in the subdermal area. Control group: patients with burn scars in the marked half of the scar who receive the intervention of normal saline injection in the subdermal area.

Main outcome variables

Vascularity; Pigmentation; Thickness; Relief; Pliability; Surface area Pain; Itching; Color; Stiffness; Thickness; Irregularity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221012056155N1**

Registration date: **2023-01-29, 1401/11/09**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-29, 1401/11/09**

Update count: **0**

Registration date

2023-01-29, 1401/11/09

Registrant information

Name

Seyed Ehsan Mousavi Lajimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8835 1450

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-31, 1401/10/10

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of autologous fat transfer on the quality of burn-induced scars	
Public title	Placebo
A randomized controlled double-blinded clinical trial	Used
Purpose	Assignment
Supportive	Parallel
Inclusion/Exclusion criteria	Other design features
Inclusion criteria:	Secondary Ids
Burn-induced scars anywhere on the trunk or limbs or face or neck The minimal interval between burn injury and intervention(fat grafting) should not be less than one year(Mature Scars)	empty
Exclusion criteria:	Ethics committees
Any significant systemic disease or morbidity (e.g. Cardiac disease, Endocrine disease, Respiratory Disease etc) Any patient with an American Society of Anesthesiologist Physical Status Classification System score>II indicating increased anesthesia risk Low Body Mass Index (BMI) (Less than 19kg/m ²) Known Systemic Immune Disorder (Acquired or inherited immune deficiency)	1
Age	Ethics committee
From 18 years old to 60 years old	Name of ethics committee
Gender	Research Ethics Committees of School of Medicine, Iran University of Medical Sciences
Both	Street address
Phase	21st St, Yousef Abad St, District 6, Tehran, Fatemeh Hospital
N/A	City
Groups that have been masked	Tehran
- Participant - Care provider - Outcome assessor	Province
Sample size	Tehran
Target sample size: 20	Postal code
More than 1 sample in each individual	IR.IUMS.FMD.REC.1401
Number of samples in each individual: 2	Approval date
Scar quality assessment based on the Patient Observer Scar Assessment Scale (POSAS) measured before intervention and 3 months after intervention in two scar halves (Autologous fat injection versus normal saline)	2022-12-31, 1401/10/10
Randomization (investigator's opinion)	Ethics committee reference number
Randomized	IR.IUMS.FMD.REC.1401.485
Randomization description	Health conditions studied
Every patient will be coded with the letter A or B using sealed envelopes. Each scar will be divided into two halves: A will be right or Up and B means left or down half. Group A will be injected with fat in right or upside half of the targeted scar and injected with normal saline in the left or downside half of the targeted scar. Group B will be injected with fat in the left or downside half of the targeted scar and injected with normal saline in the right or upside half of the targeted scar.	1
Blinding (investigator's opinion)	Description of health condition studied
Double blinded	Scars
Blinding description	ICD-10 code
The people listed below will be kept blind to the treated halves until the end of data collection: Main researcher The clinical investigator evaluates patients before the procedure and the Physicians who evaluate the outcomes Clinical care providers after the procedure Participants	L90.5
	ICD-10 code description
	Scar conditions and fibrosis of skin
	2
	Description of health condition studied
	Burn of head, face, and neck sequela
	ICD-10 code
	T20.00XS
	ICD-10 code description
	Burn of unspecified degree of head, face, and neck, unspecified site, sequela
	3
	Description of health condition studied
	Burn of trunk sequela
	ICD-10 code
	T21.00XS
	ICD-10 code description
	Burn of unspecified degree of trunk, unspecified site, sequela

4

Description of health condition studied

Burn of limbs sequela

ICD-10 code

T22.00XS

ICD-10 code description

Burn of unspecified degree of shoulder and upper limb, except wrist and hand, unspecified site, sequela

5

Description of health condition studied

Burn of Lower Limb sequela

ICD-10 code

T24.009S

ICD-10 code description

Burn of unspecified degree of unspecified site of unspecified lower limb, except ankle and foot, sequela

6

Description of health condition studied

hypertrophic scar

ICD-10 code

L91.0

ICD-10 code description

Hypertrophic scar

Primary outcomes

1

Description

Overall Scar Score (Observer)

Timepoint

Before intervention and three months after intervention

Method of measurement

Patient and Observer Scar Assessment Scale (POSAS)
Questionnaire

2

Description

Overall Scar Score (Patient)

Timepoint

Before intervention and three months after intervention

Method of measurement

Patient and Observer Scar Assessment Scale (POSAS)
Questionnaire

Secondary outcomes

1

Description

Scar Vascularity

Timepoint

Before interventions and three months after intervention

Method of measurement

Patient and Observer Scar Assessment Scale (POSAS)
Questionnaire

2

Description

Scar Pigmentation (Observer Score)

Timepoint

Before interventions and three months after intervention

Method of measurement

Patient and Observer Scar Assessment Scale (POSAS)
Questionnaire

3

Description

Scar Thickness (Observer Score)

Timepoint

Before interventions and three months after intervention

Method of measurement

Patient and Observer Scar Assessment Scale (POSAS)
Questionnaire

4

Description

Scar Relief (Observer Score)

Timepoint

Before interventions and three months after intervention

Method of measurement

Patient and Observer Scar Assessment Scale (POSAS)
Questionnaire

5

Description

Scar Pliability (Observer Score)

Timepoint

Before interventions and three months after intervention

Method of measurement

Patient and Observer Scar Assessment Scale (POSAS)
Questionnaire

6

Description

Scar Surface Area

Timepoint

Before interventions and three months after intervention

Method of measurement

Patient and Observer Scar Assessment Scale (POSAS)
Questionnaire

7

Description

Scar Pain

Timepoint

Before interventions and three months after intervention

Method of measurement

Patient and Observer Scar Assessment Scale (POSAS)
Questionnaire

8

Description

Scar Itching

Timepoint

Before interventions and three months after intervention

Method of measurement

Patient and Observer Scar Assessment Scale (POSAS)
Questionnaire

9

Description

Scar Color Difference (Patient Score)

Timepoint

Before interventions and three months after intervention

Method of measurement

Patient and Observer Scar Assessment Scale (POSAS)
Questionnaire

10

Description

Scar Stiffness (Patient Score)

Timepoint

Before interventions and three months after intervention

Method of measurement

Patient and Observer Scar Assessment Scale (POSAS)
Questionnaire

11

Description

Scar Thickness (Patient Score)

Timepoint

Before interventions and three months after intervention

Method of measurement

Patient and Observer Scar Assessment Scale (POSAS)
Questionnaire

12

Description

Scar Irregularity (Patient Score)

Timepoint

Before interventions and three months after intervention

Method of measurement

Patient and Observer Scar Assessment Scale (POSAS)
Questionnaire

Intervention groups

1

Description

First, the subcision and release of adhesions in the subdermal area of the specified location for fat injection are performed with a standard blunt cannula with a diameter of 1.5 mm. Autologous fat is harvested by Coleman's standard technique (with a 10 ml syringe connected to a blunt cannula with a diameter of 3 having several side holes at the end with a diameter of 2 mm) from the abdomen or side or medial thigh and then separating the fat by transferring it through a standard connector. 3 mm disposable syringe to a 2.5 ml syringe and placed in a centrifuge for 3 minutes with a rotation rate of 1200 rpm, and then the oil collected on the

syringes and the bloody liquid contained at the bottom Syringes are thrown away. A standard 3 mm disposable connector transfers the separated fat to a 1 ml syringe with a lower lock. And in the marked half of the scar, using this 1 ml syringe connected to a blunt cannula with a diameter of 0.7 ml with a hole (Spon Tip), fat injection is performed under the scar at the rate of 0.4 ml per square centimeter in the subdermal area.

Category

Treatment - Surgery

2

Description

Control group: First, subcision and release of adhesions of the semi-scarred subdermal area are performed for normal saline injection with a blunt standard cannula with a diameter of 1.5 mm. Then, normal saline injection with a volume equal to the injected fat is performed in the subdermal area using a 1 ml syringe connected to a blunt cannula with a diameter of 0.7 with a hole (Spoon Tip).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Fatemeh Hospital

Full name of responsible person

Fatemeh Faraji

Street address

21st St, Asad Abadi St, Tehran

City

Tehran

Province

Tehran

Postal code

1433933111

Phone

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Email

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Web page address

<https://crtfatima.iums.ac.ir/>

2

Recruitment center

Name of recruitment center

Motahhari Burn Hospital

Full name of responsible person

Alireza Shiri

Street address

Motahhari Burn Hospital, Yesmi St, Vali-Asr St, Tehran

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Province

Tehran

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Web page address
<https://crtm.iums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hossein Keyvani
Street address
5th floor, Main Building, Iran university of medical sciences, Hemmat Exp way, Tehran
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Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Email
keyvani.hi@ums.ac.ir
Grant name
Grant code / Reference number
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
Seyyed-ehsan Mousavi-lajimi
Position
Sub-speciality Resident
Latest degree

Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available