

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of assessing the effect of using adipose-derived stem cells in improving trauma, surgical and burn induced hypertrophic scars

Protocol summary

Summary

This is a clinical trial study to assess the effect of using adipose-derived stem cells in improving trauma, surgical and burn induced hypertrophic scars. For this purpose we include patients from Fatemeh Hospital with hypertrophic scar due to trauma, burn or surgery after obtaining written informed consent and informing about the method of study with convenience sampling method. In the initial phase of this study, first we do liposuction of periumbilical region with local anesthesia as an outpatient procedure, and then fat derived stem cells, after culture and cell characterization, are sent to the research executive. Photos will be taken of all scars before any intervention and will be scored with Vancouver scoring system. The scar is divided into two equal halves. We inject normal saline in one half and fat derived stem cells in the other half with the same volumes. Patients will be examined at 3, 6 months and 1 year after injection, taken photos and their scars will be scored.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012070710201N1**
Registration date: **2012-10-04, 1391/07/13**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-10-04, 1391/07/13

Registrant information

Name

Ali asghar Salahi kojoor

Name of organization / entity

Iran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 21 2640 8735

Email address

a-abbaszadeh@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2012-10-06, 1391/07/15

Expected recruitment end date

2013-03-05, 1391/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of assessing the effect of using adipose-derived stem cells in improving trauma, surgical and burn induced hypertrophic scars

Public title

The role of stem cells in hypertrophic scar improvement

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with hypertrophic scar.

Exclusion criteria: Patient's reluctance to continue cooperation.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University Of Medical Sciences

Street address

Tehran University Of Medical Sciences, Hemat campus, Hemat High Way

City

Tehran

Postal code

Approval date

2012-08-07, 1391/05/17

Ethics committee reference number

9003121493162041

Health conditions studied

1

Description of health condition studied

Hypertrophic Scar

ICD-10 code

L91.0

ICD-10 code description

Hypertrophic scar

Primary outcomes

1

Description

Vascularity

Timepoint

3, 6 months and 1 year

Method of measurement

Inspection

2

Description

Pigmentation

Timepoint

3, 6 months and 1 year

Method of measurement

Inspection

3

Description

pliability

Timepoint

3, 6 months and 1 year

Method of measurement

palpation

4

Description

Height

Timepoint

3, 6 months and 1 year

Method of measurement

Measurement with caliper

5

Description

Vancouver Scoring System

Timepoint

3, 6 months and 1 year

Method of measurement

Inspection and Palpation

Secondary outcomes

1

Description

Scar Tissue Increment

Timepoint

3, 6 months and 1 year

Method of measurement

Inspection and measurment with caliper

2

Description

Pruritus

Timepoint

3, 6 months and 1 year

Method of measurement

Patient Expression

3

Description

Burning

Timepoint

3, 6 months and 1 year

Method of measurement

Patient Expression

4

Description

Injection Site Infection and Inflammation

Timepoint

Up to 1 month

Method of measurement

Diagnosis by physician

Intervention groups

1

Description

0.5 cc N/S injection per 1 square Cm of controls scar

Category

Placebo

2

Description

0.5 cc fat derived stem cell injection per 1 square cm of cases scar

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Fatemeh Hospital

Full name of responsible person

Abolfazl Abbaszadeh

Street address

21st st. Yousefabad

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University Of Medical Sciences

Full name of responsible person

Dr. Masoud Younesian

Street address

Pour sina Ave, Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University Of Medical Sciences

Full name of responsible person

Abolfazl Abbaszadeh

Position

Plastic Surgery Resident

Other areas of specialty/work

Street address

21st st. Yousefabad, Hazrat Fatemeh Hospital

City

Tehran

Postal code

Phone

+98 21 8871 0099

Fax

Email

a-abbaszadeh@razi.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University Of Medical Sciences

Full name of responsible person

Aliasghar Salahi kojoor

Position

Plastic Surgery Resident

Other areas of specialty/work

Street address

21st st. Yousefabad, Hazrat Fatemeh Hospital

City

Tehran

Postal code

Phone

+98 21 8871 0099

Fax

Email

a-abbaszadeh@razi.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University Of Medical Sciences

Full name of responsible person

Aliasghar Salahi kojoor

Position

Pastic Surgery Resident

Other areas of specialty/work**Street address**

21st st. Yousefabad, Hazrat Fatemeh Hospital

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Postal code**Phone**

+98 21 8871 0099

Fax**Email**

a-abbaszadeh@razi.tums.ac.ir

Web page address**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