Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 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

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Recruitment status

Recruitment complete

Funding source

Tehran university of medical scinces

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
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Plastic Surgery Resident
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Person responsible for scientific inquiries

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Person responsible for updating data

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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