

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of amniotic membrane loaded with adipose-derived stem cells on skin graft donor site and 3rd degree burn wound healing

Protocol summary

Summary

This study is designed to evaluate effects of stem cells on healing skin graft donor sites and third degree burn wounds. It is a randomized, clinical trial, which will be done on 20 patients (10 skin graft and 10 burn patients). These patients' inclusion criteria include: age of 18 - 60 years old, who require skin graft surgery, or those who have third degree burn of less than 10% of TBSA. Exclusion criteria include: having co-morbidity. In all the patients, 30 ml of fat will be suctioned from the abdominal area under local anesthesia. Its stem cells will be then separated and cultured. Cell characteristics will be determined after appropriate passage. Afterwards, these stem cells will be transferred to amnion, which become acellular enzymatically. The skin graft donor wound in thigh will be divided to medial, lateral and middle parts. Then, each part will be randomly covered by 1- acellular amnion loaded with stem cell, 2- acellular amnion and 3- Vaseline gauze. In the second group of patients, burning scar will be removed during the surgery. Wound site will be divided to three parts and covered in a similar fashion to the first group. Healing speed of the wounds, characteristics of scar and histopathology criteria will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209178177N5**
Registration date: **2013-06-12, 1392/03/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-12, 1392/03/22

Registrant information

Name

Mohammad Javad Fatemi

Name of organization / entity

Burn Research Center of Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 4275

Email address

mj-fatemi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Bonyakhte Institute

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2017-03-15, 1395/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of amniotic membrane loaded with adipose-derived stem cells on skin graft donor site and 3rd degree burn wound healing

Public title

Effect of amniotic membrane loaded with adipose-derived stem cells on skin graft

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Eighteen to sixty years old patients
2. Needing skin graft surgery or with 3rd degree burn

less than 10% of TBSA 3. signing informed consent
Exclusion criteria: Co-morbidity

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Central Department of Tehran University of Medical Sciences, Keshavarz Blvd, Tehran

City

Tehran

Postal code

1417653761

Approval date

2013-04-22, 1392/02/02

Ethics committee reference number

90-01-129-13379-80780

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

T20, T21,

ICD-10 code description

Burns and corrosions of external body surface, specified by site

Primary outcomes

1

Description

Wound healing

Timepoint

Every other day after surgery

Method of measurement

Observation, Examination, Photography

2

Description

Epithelization

Timepoint

One month after surgery

Method of measurement

Observation, Examination, Photography, Biopsy

Secondary outcomes

1

Description

Infection

Timepoint

5 days after surgery

Method of measurement

Wound Culture

2

Description

Scar

Timepoint

Six months and one year after surgery

Method of measurement

Vancouver Scar Scale

Intervention groups

1

Description

Intervention 1: Coverage of the skin graft donor site or burn wound with acellular amnion loaded with fat derived-stem cell. The dressing will be changed after 5 days and then every other day till complete healing of the wound.

Category

Treatment - Other

2

Description

Intervention 2: Coverage of skin graft donor site or burn wound with acellular amnion. The dressing will be changed after 5 days and then every other day till complete healing of the wound.

Category

Treatment - Other

3

Description

Control group: Coverage of skin graft donor site or burn wound with Vaseline gauze. The dressing will be changed after 5 days and then every other day till the complete healing of the wound.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Fatima Hospital

Full name of responsible person

Mohammad Javad Fatemi

Street address

Hazrat Fatima Hospital, Seyed Jamaledin Asadabadi Ave, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Central Department of Tehran University of Medical Sciences, Keshavarz Blvd, Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research of 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

Hazrat Fatima Hospital

Full name of responsible person

Mohammad Javad Fatemi

Position

Associate Professor of Plastic and Reconstructive Surgery

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

Hazrat Fatima Hospital, Seyed Jamaledin Assadabadi Ave, Tehran

City

Tehran

Postal code

1433933111

Phone

+98 21 8871 7272

Fax

+98 21 8872 3150

Email

mj-fatemi@sins.tums.ac.ir

Web page address

<http://medicine.tums.ac.ir/default.aspx?p=730>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hazrat Fatima Hospital

Full name of responsible person

Mohammad Javad Fatemi

Position

Associate Professor of Plastic and Reconstructive Surgery

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

Hazrat Fatima Hospital, Seyed Jamaledin Asadabadi Ave, Tehran

City

Tehran

Postal code

1433933111

Phone

+98 21 8871 7272

Fax

+98 21 8872 3150

Email

mj-fatemi@sina.tums.ac.ir

Web page address

<http://medicine.tums.ac.ir/default.aspx?p=730>

Person responsible for updating data

Contact

Name of organization / entity

Hazrat Fatima Hospital

Full name of responsible person

Mohammad Javad Fatemi

Position

Associate professor of Plastic and Reconstructive
Surgery

Other areas of specialty/work

Street address

Hazrat Fatima Hospital, Seyed Jamaledin Asadabadi
Ave, Tehran

City

Tehran

Postal code

1433933111

Phone

+98 21 8871 7272

Fax

+98 21 8872 3150

Email

mj-fatemi@sina.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