Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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Iran (Islamic Republic of)
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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 Bvld, 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 Jamaleddin Asadabadi Ave, Tehran

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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 Bvld, Tehran

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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

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Person responsible for updating data

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Web page address
http://medicine.tums.ac.ir/default.aspx?p=730

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