Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of Acellular Amniotic membrane loaded by cultured fetal fibroblast cells in split thickness skin wound healing

Protocol summary

Summary

This study is designed to evaluate the effect of fetal fibroblast on partial thickness wound healing. It is a double blind, randomized clinical trial which will be done on 10 patients who need skin graft surgery. Fetal fibroblast preparation: [Inclusion criteria are pregnant women, who are older than 18 years old and must have abortion, aborted fetus with age of 11 to 14 weeks, and filling out the informed consent. Exclusion criteria included pregnant women who are younger than 18 years old, aborted fetus younger than 11 weeks or older than 14 weeks, infectious diseases (HIV-HBV-HCV) and consumption of immune-suppressive drugs. After selecting the appropriate fetus, a 10×10 specimen of skin will be harvested and sent to Royan Institute for fibroblast isolation and culture. Clinical part of the trial has the following inclusion criteria: patients with age of 20 to 60 years old, those who need skin graft surgery, filling out the informed consent. Its exclusion criterion is co-morbidity. After harvesting skin graft, three 5×5 cm areas will be selected in lateral, anterior and medial parts of donor for examination. One of these areas will be randomly covered with acellular amnion loaded with fetal fibroblast; the second part will be covered with acellular amnion and the third one with Vaseline gauze. The surgeon who is dressing the wound is blind about type of the amnion. Speed of wound healing, pain, infection, scar and pathologic criteria of all the patients will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302218177N6**
Registration date: **2013-06-29, 1392/04/08**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-06-29, 1392/04/08

Registrant information

Name
Mohammad Javad Fatemi
Name of organization / entity
Burn Research Center of Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Royan Institute

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Acellular Amniotic membrane loaded by cultured fetal fibroblast cells in split thickness skin wound healing

Public title

The effects of fetal fibroblast in skin wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Laboratory inclusion criteria: 1. Pregnant women who are older than 18 years old that had to be aborted 2. Filling informed consent 3. Aborted fetus with the age of 11 to 14 weeks 4.Lack of infectious diseases (HIV-HBV-HCV) 5.Lack consumption of immune-suppressive and cytotoxic drugs during past 6 months Laboratory exclusion criteria: 1. Aborted fetus that is younger than 11 weeks or older than 14 weeks 2.Pregnant women who are younger than 18 years old Clinical inclusion criteria: 1.Patients with the age of 20 to 60 years old 2. Those who need skin graft surgery 3.The extent of surgical site wound 10-30% 4. Filling informed consent 5. Lack of co-morbidity Clinical exclusion criteria: 1.Under the age of 20 years and above 60 years 2.The extent of surgical site wound more than 30% and less than 10% 3.Lack of informed consent

Age

From **8 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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

91-03-129-18724-80782

Health conditions studied

1

Description of health condition studied

Skin Wound

ICD-10 code

T14.1

ICD-10 code description

Open wound of unspecified body region

Primary outcomes

1

Description

Wound healing

Timepoint

Examination and photography on 3, 5, 7, 11, 13 and 15 days and 1 month after surgery - biopsy on 7 dayس after surgery

Method of measurement

Observation and Examination and Biopsy

Secondary outcomes

1

Description

Pain

Timepoint

Three, five, seven, nine, eleven, thirteen and fifteen days after surgery

Method of measurement

Visual Analogue Scale

2

Description

Infection

Timepoint

Seven and fifteen days after surgery

Method of measurement

Examination, Wound Culture

3

Description

Scar

Timepoint

Three and six months after surgery

Method of measurement

Vancouver Scar Scale

Intervention groups

1

Description

Intervention 1: Coverage of the skin graft donor site with acellular amnion loaded with cultured fetal fibroblast cell. The dressing will be changed every other day till complete healing of the wound after 3 days.

Category

Treatment - Other

2

Description

Intervention 2: Coverage of the skin graft donor site with acellular amnion. The dressing will be changed every other day till complete healing of the wound after 3 days.

Category

Treatment - Other

3

Description

Control group: Coverage of the skin graft donor site with Vaseline gauze. The dressing will be changed every other day till complete healing of the wound after 3 days.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Burn Hospital

Full name of responsible person

Mohammad Javad Fatemi

Street address

Shahid Motahari Burn Hospital, Rashid Yasami Ave, Vali Asr Ave, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of Medical

Full name of responsible person

Akbar Fotouhi

Street address

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

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

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Person responsible for scientific inquiries

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Mohammad Javad Fatemi

Position

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Other areas of specialty/work

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Person responsible for updating data

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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