

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of amniotic membrane extract drops in wound healing of semi-thickness skin donor site in human models

Protocol summary

Summary

We conducted this study to evaluate the effect of amniotic membrane extract drops in semi-thickness skin wound healing. This study is a triple blind randomized clinical trial on 46 patients in need of skin graft surgery. Inclusion criteria: age 18-65 years, requiring skin graft surgery, informed consent Exclusion criteria: Removal of skin graft from the outside of the thigh, conditions and diseases in which the immune system is weakened and wound healing is delayed such as: diabetes, cancer, immune system dysfunction, drugs that suppress the immune system, taking corticosteroids, smoking and alcohol, patients who do not cooperate with treatment and referrals necessary after surgery. Drops deliverer, divides patients randomly by software into two groups. Amniotic membrane extract drops and placebo in identical containers labeled with the patient's name will be sent to the therapist. Skin transplant surgery will be performed in all patients only by one surgeon with the same technique in the patient's groin area. The patient, surgeon and someone who analyzes data are blind to study groups. Skin donor site in two groups is dressed with gauze soaked in amniotic extract and placebo respectively. In all patients wound site in terms of wound healing, pain, infection, cost and scarring will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201703148177N16**

Registration date: **2017-04-03, 1396/01/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-04-03, 1396/01/14

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

Iran University of Medical Sciences

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2020-02-04, 1398/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of amniotic membrane extract drops in wound healing of semi-thickness skin donor site in human models

Public title

Amniotic membrane extract drops in wound healing of semi-thickness skin donor site

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18-65 years old; requiring skin graft surgery; signing informed consent. Exclusion criteria: removal of skin graft from the outside of the thigh; conditions and diseases in which the immune system is weakened and wound healing is delayed such as: diabetes, cancer, immune system dysfunction, drugs that suppress the immune system, taking corticosteroids, smoking and alcohol; patients who do not cooperate with treatment and referrals necessary after surgery.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Central building of the University of Medical Sciences,
Hemmat Highway

City

Tehran

Postal code

1449614535

Approval date

2017-03-14, 1395/12/24

Ethics committee reference number

IR.IUMS.REC.1395.29782

Health conditions studied

1

Description of health condition studied

Wound

ICD-10 code

T14.1

ICD-10 code description

Open wound of unspecified body region

Primary outcomes

1

Description

Wound Healing

Timepoint

Observation, examination and photography on days 1 and 12 after surgery and during spontaneous separation of Vaseline gauze from wound

Method of measurement

Observation, examination and photography

Secondary outcomes

1

Description

Cost

Timepoint

The end of the study

Method of measurement

Cost estimation of the number of drops used in each treatment group

2

Description

Scar

Timepoint

6 months after surgery

Method of measurement

Vancouver Scar Scale, Patient and Observer Scar Assessment Scale (POSAS)

3

Description

Infection

Timepoint

Every 3 days after surgery until complete wound healing

Method of measurement

Observation, examination and wound culture

4

Description

Pain

Timepoint

3, 6 and 12 days after surgery

Method of measurement

Visual Analogue Scale (VAS)

Intervention groups

1

Description

Intervention group: Wound covering of donor site of skin transplantation with amniotic membrane extract drops. From the day of surgery, dressing is changed every 3 days until complete wound healing

Category

Treatment - Drugs

2**Description**

Control group: Wound covering of donor site of skin transplantation with solvent amniotic membrane extract drops (normal saline). From the day of surgery, dressing is changed every 3 days until complete wound healing

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hazrat Fatima Hospital

Full name of responsible person

Mohammad Javad Fatemi

Street address

Tehran, Asad Abadi street, Hazrat Fatima Hospital

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Ali Javad Mousavi

Street address

Tehran, Central building of the University of Medical Sciences

City

Tehran

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source**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

2**Sponsor****Name of organization / entity**

Added at 2017-08-20: Royan Institute for Stem Cell Biology and Technology (RI-SCBT)

Full name of responsible person

Added at 2017-08-20: Marzieh Ebrahimi

Street address

Royan Institute for Stem Cell Biology and Technology (RI-SCBT), number 82, Akbari alley, Ejazi Ave, Zafaranih, Tehran

City

Added at 2017-08-20: Tehran

Grant name

1396/5/29 پروژرسانی:

Grant code / Reference number

1396/5/29 پروژرسانی:

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

Yes

Title of funding source

Added at 2017-08-20: Royan Institute for Stem Cell Biology and Technology (RI-SCBT)

Proportion provided by this source**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**

Burn Research Center

Full name of responsible person

Tooran Bagheri

Position

Master of Nursing

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

Shahid Motahari Hospital, Rashid Yasemi Street, Vali-e-asr Avenue, Tehran

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inquiries

Contact

Name of organization / entity

Burn Research Center

Full name of responsible person

Mohammad Javad Fatemi

Position

Plastic and Reconstructive surgeon

Other areas of specialty/work

Street address

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Contact

Name of organization / entity

Hazrat Fatima Hospital

Full name of responsible person

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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