Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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, Zaferanieh, Tehran

City

Added at 2017-08-20: Tehran

Grant name

بروزرسانی 1396/5/29:

Grant code / Reference number

بروزرسانی 1396/5/29:

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

City

Tehran

Postal code

1196714353

Phone

+98 21 8888 4275

Fax

Email

tooran_bagheri@yahoo.com

Web page address

Person responsible for scientific

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

City
Tehran

Postal code
1196714353

Phone
+98 21 8888 4275

Fax

Email
mj-fatemi@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Hazrat Fatima Hospital

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

City
Tehran

Postal code
1196714353

Phone
+98 21 8888 4275

Fax

Email
tooran_bagheri@yahoo.com

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