

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Clinical trial of the decellularized amniotic membrane for dressing of skin wounds

Protocol summary

Study aim

Evaluation of the safety and efficacy of the decellularized amniotic membrane of Sina Mehr Fajr Mazandaran company with Epos AmnioHeal® brand in skin burn wounds

Design

The clinical trial has an experimental group and a control group, three blind strains randomized on 60 patients in three centers. A coin toss will be used for randomization.

Settings and conduct

The present study is carried out in three centers: Zare Sari Burn Hospital, Fifth Azar Hospital, Gorgan, and Shahid Dr. Beheshti Hospital, Babol. This study aims to investigate the effectiveness and local safety of Epos AmnioHeal® dressing in burn wound healing compared to a similar commercial dressing. The way of dressing the wound is that first the wound is washed with sterile distilled water and then it is covered with a dressing. The patient is not aware of the type of dressing used in each part of the wound, and the surgeon, nurse, and evaluating doctor are three different people.

Participants/Inclusion and exclusion criteria

Second degree burn patients are selected from those who refer to the target hospitals. Inclusion criteria: Patients with skin wounds (burn trauma, diabetes, bedsores, etc.) after entering the hospital. There is no age or gender restriction. Exclusion criteria: Cases such as having severe vascular lesions, active or latent infection, or uncontrolled infection at the wound site can prevent the effectiveness of this allograft. Oposamnihyl should not be used to treat lesions that do not have a definitive diagnosis. In patients with metabolic, heart, kidney, liver, blood, autoimmune or any other major diseases, this product should not be used without the permission of the attending physician.

Intervention groups

Intervention group A: Epos AmnioHeal® dressing.
Intervention group B: Commercial amniotic membrane dressing

Main outcome variables

Rate and speed of recovery; pain; inflammation; wound size & fever

General information

Reason for update

Acronym

AM

IRCT registration information

IRCT registration number: **IRCT20230429058021N1**

Registration date: **2023-05-22, 1402/03/01**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-22, 1402/03/01**

Update count: **0**

Registration date

2023-05-22, 1402/03/01

Registrant information

Name

Mazaher Gholipourmalekabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4614

Email address

mazaher.gholipour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-08-21, 1402/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the decellularized amniotic membrane for dressing of skin wounds

Public title

Safety and effectiveness evaluations of amniotic membrane wound dressing

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with skin wounds (second degree burn trauma) after entering the hospital.

Exclusion criteria:

Cases such as having severe vascular lesions, active or latent infection, or uncontrolled infection at the wound site can prevent the effectiveness of this allograft. Oposamniohyl should not be used to treat lesions that do not have a definitive diagnosis. In patients with metabolic, heart, kidney, liver, blood, autoimmune or any other major diseases, this product should not be used without the permission of the attending physician.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

In each center, the samples are selected from consecutive patients using simple randomization method (tossing a coin). After that, the background characteristics of the patients in each group are evaluated

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient is unaware of the type of dressing used in each part of the wound, that is, he does not know which dressing is the main group and which is the control group. On the other hand, the surgeon who performs the dressing, the experienced nurse who records the history, and the doctor who evaluates the treatment result are three separate people. In this way, photos and histories are prepared and coded according to the checklist of the intervention and wound control parts at the designated

times by the nurse (who is independent from the dressing and evaluator) and the photos are taken by the evaluating doctor who is from The type of dressing used in each photo is unknown, it is checked and the results are recorded.

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Valie-Asr Boulevard, Sari, Mazandaran, Iran

City

Sari

Province

Mazandaran

Postal code

48471-93696

Approval date

2023-04-16, 1402/01/27

Ethics committee reference number

IR.MAZUMS.REC.1402.17607

Health conditions studied**1****Description of health condition studied**

Patients with second degree skin burns

ICD-10 code

T21.2

ICD-10 code description

Burn of second degree of trunk

Primary outcomes**1****Description**

Time and size (area) of the wound according to the CRF form

Timepoint

0, 3, 6, 9, 12, 15, 18 and 21 days after primary transplantation

Method of measurement

Observation and measurement of wound area

2

Description

Wound granulation according to the CRF form

Timepoint

0, 3, 6, 9, 12, 15, 18 and 21 days after primary transplantation

Method of measurement

Observation by a wound specialist

3

Description

Redness, discharge, apparent infection, unpleasant odor and other inflammatory reactions according to the CRF form

Timepoint

0, 3, 6, 9, 12, 15, 18 and 21 days after primary transplantation

Method of measurement

Observation and examination of the patient by a specialist doctor

4

Description

Pain level according to the CRF form

Timepoint

0, 3, 6, 9, 12, 15, 18 and 21 days after primary transplantation

Method of measurement

Examination of the patient by a specialist doctor

5

Description

Check the fever according to the CRF form

Timepoint

0, 3, 6, 9, 12, 15, 18 and 21 days after primary transplantation

Method of measurement

Thermometer

Secondary outcomes

1

Description

Wound healing time

Timepoint

Every 3 days to 21 days

Method of measurement

Patient examination and visual inspection

2

Description

Wound size

Timepoint

Every 3 days to 21 days

Method of measurement

Visual inspection and ruler

3

Description

Redness and inflammation

Timepoint

Every 3 days to 21 days

Method of measurement

Patient examination and visual inspection

4

Description

Pain

Timepoint

Every 3 days to 21 days

Method of measurement

Patient examination

Intervention groups

1

Description

Intervention group: After selecting the patients and obtaining written consent from the patient or his/her legal guardian, the wound after washing with normal saline is covered with the amniotic membrane product of the current study and three layers of sterile gauze are placed on it. If the wound has a lot of exudate, the dressing will be changed every day. In cases of less exudate, it is changed every three to five days

Category

Treatment - Surgery

2

Description

Control group: After selecting the patients and obtaining written consent from the patient or his/her legal guardian, the wound after washing with normal saline is covered with the commercial amniotic membrane product (Baft Iranian) and three layers of sterile gauze are placed on it. If the wound has a lot of exudate, the dressing will be changed every day. In cases of less exudate, it is changed every three to five days

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Zare Burn Hospital

Full name of responsible person

Dr Mohammadhossein Hesami Rostami

Street address

Zare Burn Hospital, 3rd km Sari-Neka Rd.

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Mazandaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sina Mehr Fajr Co.
Full name of responsible person
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Sina Mehr Fajr Bldg., Keshavarz Blvd.
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sina Mehr Fajr Co.
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The results obtained according to the CRF file, such as healing speed, wound size, redness, inflammation, fever, etc. during treatment. All the results are coded, each code identifies the patient's personal information. The patient's personal information will only be available to the project manager.

When the data will become available and for how**long**

The information that can be presented after the completion of the project and the analysis of the results will be presented in scientific journals or in the congress.

To whom data/document is available

Only respected project managers will have access to the results of the patient's personal information. The information of the results of the study will be available to all people without mentioning the patient in the form of a scientific article. It is worth mentioning that this study is for the approval of the production license of this product by Sina Mehr Fajr Mazandaran.

Under which criteria data/document could be used

The information of this study will also be provided to the Food and Drug department of Mazandaran University of Medical Sciences or the medical equipment and supplies department of the Tehran Food and Drug Administration.

From where data/document is obtainable

Respected executors of the plan

What processes are involved for a request to access data/document

After the end of this project, the results of the study will be published as a scientific paper and available online. Although someone needs the results in more detail, he can request scientific data (not the patient's person) from the author of the article through the email provided in the section responsible for the article.

Comments