Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 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. 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.

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)
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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
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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
Mohammadreza Mahdavi Amiri
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Sina Mehr Fajr Bldg., Keshavarz Blvd.
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Mazandaran
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4819787441
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Mahdavi899@gmail.com
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
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Amir Mellati
Position
Assistant Professor
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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