Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of the efficacy of amnion dressing in wound healing of skin graft donor sites (superficial second-degree wound) in the lateral thigh and its comparison with conventional wound dressing

Protocol summary

Study aim
Determining and comparing the effect of amnion dressing on healing superficial second-degree burns wounds

Design
Two arms parallel-group randomized trial with a control group and blinded participants and phase 2 on 58 patients. The blocking method was used for randomization.

Settings and conduct
This study is performed in the burn department of Imam Reza Hospital. 58 patients with deep second-degree burns (less than 20% of burns) who require skin grafts are randomly assigned into two groups based on clinical symptoms confirmed by an infectious disease specialist and a plastic and burn surgeon. Group A patients receive amnion dressing and then dry gauze and bandaging, and group B patients receive the usual treatment (a layer of fatty gauze, dry gauze, and then bandaging). Every 48 hours, the secondary dressing, which includes dry gauze and a bandage, is replaced, and the donor site is evaluated in terms of infection and the progress of wound healing. An infectious disease specialist and a plastic and burn surgeon perform monitor all patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients between the ages of 15 and 55 are eligible to participate. Have a severe burn of grade 2 or higher that requires a skin graft Patients with burns that are less than or equal to 20% Patient with deep second degree burns in upper and lower limbs and anterior trunk except for lateral thigh Criteria for not including people in the study: Patients under 15 years and over 55 years Patients with more than 20% burns Burns in the lateral thigh area

Intervention groups
The intervention group consisted of 29 patients who underwent amnion dressing in their lateral thighs.

Main outcome variables
Duration of complete wound healing in the two groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210918052511N1**
Registration date: **2021-09-24, 1400/07/02**
Registration timing: **prospective**

Last update: **2021-09-24, 1400/07/02**
Update count: **0**

Registration date
2021-09-24, 1400/07/02

Registrant information

Name
Omid Yazarlu

Name of organization / entity

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Iran (Islamic Republic of)

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+98 51 3841 2073

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yazarlouom@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-22, 1400/07/30

Expected recruitment end date
2022-02-19, 1400/11/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the efficacy of amnion dressing in wound healing of skin graft donor sites (superficial second-degree wound) in the lateral thigh and its comparison with conventional wound dressing

Public title

Assessment of the efficacy of amnion dressing in wound healing of skin graft donor sites

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between the ages of 15 and 55 are eligible to participate. Have a severe burn of grade 2 or higher that requires a skin graft Patients with burns that are less than or equal to 20% Patient with deep second degree burns in upper and lower limbs and anterior trunk except lateral thigh

Exclusion criteria:

Patients who are receiving chemotherapy Patients taking corticosteroids or cytotoxic medicines Pregnancy Cancer, cytotoxic drugs, immunosuppressants, and the presence of chronic diseases other than diabetes that affect wound healing, such as severe vascular disease, lupus, rheumatoid arthritis, and renal failure Smoking The presence of an underlying disease leads to a defective immune system Diabetic patients Taking drugs that lead to a defective immune system. Burns in the lateral thigh area.

Age

From **15 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Each of the 58 patients would be assigned a number between 1 and 58 which is randomized by using random.org/integers in two columns. The numbers of the first column are assigned to group A and the second column is assigned to group B. With a lottery method, each column (A or B) is assigned to intervention or control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Prior to participating in the trial, all patients or their legal representatives sign an informed consent form and are informed that they will be in one of two treatment groups. After that, participants enter the operating room and receive the dressing based on how the allocation occurred, and they are unaware of the type of dressing received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

research ethics committee of school of medicine-Mashhad university of medical sciences

Street address

Azadi squer- campus of Medical University of Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

91379-13316

Approval date

2021-08-15, 1400/05/24

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.331

Health conditions studied

1

Description of health condition studied

Burn patients

ICD-10 code

T20

ICD-10 code description

Burn and corrosion of head, face, and neck

Primary outcomes

1

Description

Duration of complete wound healing

Timepoint

Every 48 hours

Method of measurement

Based on the clinical observations of an infectious disease specialist and plastic and burn surgeon

Secondary outcomes

1

Description
Wound condition, including the presence or absence (yes/no) of granulation tissue, bleeding, pain, infection, and other wound complications or healing factors are evaluated.

Timepoint
Every 48 hours

Method of measurement
Based on the scores of the variables and presence or absence (yes / no)

Intervention groups

1

Description
Intervention group: The amnion dressing is used for two weeks and this dressing is provided by Sinacell Co.Amnion membrane as a biological dressing in the treatment of burn wounds accelerates wound healing, reduces the need to change dressings, shorten the duration of hospitalization, reduce scar formation, temperature control, proper air permeability to the wound and reduce pain and earlier removal of the dressing . It is used once for dressing the donor site in the operating room and the secondary dressing (dry gauze and bandage) is changed every 48 hours.

Category
Treatment - Devices

2

Description
Control group: includes the conventional treatment (a layer of fatty gauze, dry gauze and then bandaging) for two weeks.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Burn department-Imam Reza hospital

Full name of responsible person
Dr. Omid Yazarlou

Street address
Daneshgah street-Burn department-Imam Reza hospital

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Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Khalil Abnous

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Sina Cell 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
Mashhad University of Medical Sciences

Full name of responsible person
Dr Omid Yazarlou

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Plastic & Reconstructive Surgery

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Person responsible for scientific inquiries

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Mashhad University of Medical Sciences

Full name of responsible person
Dr. Omid Yazarlou

Position
Assistant Professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
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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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Part of the data is related to the main outcome and the secondary outcome can be shared.

When the data will become available and for how long
Access period starts 3 months after the results are published

To whom data/document is available
The data is available to researchers working in academic and scientific institutions as well as people working in industry.

Under which criteria data/document could be used
Use as a reference

From where data/document is obtainable
Dr. Maede Hasanpour - Faculty of Pharmacy - Room 233 - Phon number 09113145617- maede.hasanpour@yahoo.com

What processes are involved for a request to access data/document
After making a call via email or phone, the desired data will be sent using email or post.

Comments