

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

Country

Iran (Islamic Republic of)

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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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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