Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessment of the effectiveness of hydrocolloid, silver containing dressing in the treatment of partial thickness skin graft donor sites.

Protocol summary

Study aim

Assessment of the effectiveness of hydrocolloid, silver containing dressing in the treatment of split thickness skin graft donor site

Design

Two arm Clinical trial, with a control group, with parallel groups, double-blind, on 42 patients This study includes two groups of 21 people who are assigned to each group based on the inclusion and random criteria. It is used to randomize the table of random numbers.

Settings and conduct

The study is carried out in two groups of 21 people who undergo half-thickness skin removal from the thigh area at Tehran Hazrat Fatemeh Hospital. In both groups, the skin is treated with electric tools. Then, the harvesting areas in the intervention group are dressed with silver-containing hydrocolloid dressing, and in the control group, they are dressed in the traditional way with petroleum jelly. The wound healing process and the final wound scar in two groups are investigated and compared. During the procedure, only the main researcher, who also performs the dressing, is aware of the type of dressing. But the patients, the wound care, the person who evaluates and records the findings, and the person who is in charge of the statistical analysis, none of them will have any information about the way of dressing in each person or even in each group.

Participants/Inclusion and exclusion criteria

Patients above 18 and under 60 years old who need to harvest skin graft

Intervention groups

In the intervention group, hydrocolloid dressing containing silver is used, and in the control group, traditional dressing (Vaseline gas) is used for dressing.

Main outcome variables

Wound infection, speed of wound healing, frequency of need for dressing, pain when changing dressing, final scar of wound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221210056768N1**
Registration date: **2022-12-14, 1401/09/23**
Registration timing: **prospective**

Last update: **2022-12-14, 1401/09/23**
Update count: **0**

Registration date

2022-12-14, 1401/09/23

Registrant information

Name

Amirali Mirfakhraee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2249 3050

Email address

ahiakhanahmadi1985@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effectiveness of hydrocolloid, silver containing dressing in the treatment of partial thickness skin graft donor sites.

Public title
Silver containing dressing in wound management.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who undergo split thickness skin graft Age above 18, and under 60 No interfering medical conditions Getting the informed consent
Exclusion criteria:
Age under 18, or above 60 Reluctance of the patient Any significant morbidity such as uncontrolled diabetes
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done in a simple way. Patients who meet the inclusion criteria will receive one of two different types of dressings. Of course, only the researcher will know the type of dressing used and the randomization sequence. Patients, nurses who provide care services, evaluators, and ultimately data analysts will not be aware of these things.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient does not know the type of dressing used on the wound. The nurse who performs the service of changing the external layers of the dressing is not aware of the type of the main dressing used in the lower layer. The evaluator of the results who checks the results after removing the dressing does not know what type of dressing was used in each person. The data analyst does not know who the control group and the control group are
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Science
Street address
Iran university of medical science, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1916953576
Approval date
2022-02-08, 1400/11/19
Ethics committee reference number
IR.IUMS.FMD.REC.1400.609

Health conditions studied

1

Description of health condition studied
final scar
ICD-10 code
L90.5
ICD-10 code description
Scar conditions and fibrosis of skin

2

Description of health condition studied
Reepithelialization rate
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The final scar of the wound - at the end of the first and sixth months, the quality of the scar and the scar score are evaluated based on the Vancouver scar measurement criteria, and the average scar score in the two groups is compared.
Timepoint
After 1 month, and 6 months
Method of measurement
According to the Vancouver Scar Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Using the hydrocolloid, silver containing dressing in the treatment of split-thickness skin graft donor site

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Saint Fatima, plastic and reconstructive surgery hospital

Full name of responsible person

Amirali Mirfakhraee

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21 Alley, Yousefabad Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abolfazl Abbaszade

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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

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Amirali Mirfakhraee

Position

Subspecialty student

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

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Latest degree
Specialist

Other areas of specialty/work
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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
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The results of the variables for each individual will be published, as well as the demographic information of each individual. All findings and documents, except identity information, can be published.

When the data will become available and for how long
The findings will be available three months after the publication of the results.

To whom data/document is available
All academic researchers, and commercial users and employers in the field of wound healing products can use this data.

Under which criteria data/document could be used
The use of data and results is unimpeded under any circumstances, citing the source.

From where data/document is obtainable
I, Dr. Amir Ali Mirfakhrai, as the main person in charge of the project, am ready to share the data. Applicants can send their application to the email address Dr.mirfakhrae@gmail.com.

What processes are involved for a request to access data/document
After sending the application to the mentioned email, the data will be sent to the applicant within 2 weeks.

Comments