

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation of the effectiveness of silver-containing hydrocolloid dressings in the treatment of donor wounds of partial- thickness skin grafts

Protocol summary

Study aim

Evaluation of the effectiveness of silver containing hydrocolloid dressings in the treatment of the donor site of partial- thickness skin grafts

Design

This study is a clinical trial with a control group, with parallel, double-blind and randomized groups on 30 patients. Block randomization method is used for randomization.

Settings and conduct

First, the partial- thickness skin grafts removed with an electric dermatome The donor site is then covered with epinephrine-impregnated gas at 1 in 100,000 until proper homeostasis is established. In the next step, patients are randomly divided into two groups: Hydrocolloids containing silver are made under the Aquacel Ag brand. In the first group, the donor site is first placed on the wound with a gas soaked in Vaseline and then bandaged with one or two layers of dry gas and a crepe bandage. In the second group, the donor site is done with Aquacel Ag dressing with dimensions of 15 by 15 cm or 20 by 30 cm, depending on the dimensions of the wound and according to the manufacturer's instructions, then one or two layers of dry gas are placed on this dressing and Finally, the crepe bandage is done. This study is performed in Hazrat Fatemeh Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who need partial partial-thickness skin grafts to repair skin defects for various reasons Exclusion criteria: Patients who do not wish to participate in the study Patients with previously known allergies to silver

Intervention groups

Intervention group: Patients undergoing Doner Wound treatment of partial- thickness skin grafts with silver-containing hydrocolloid dressings Control group: Patients undergoing treatment of Doner Wound treatment of partial- thickness skin grafts by traditional dressing

Main outcome variables

The degree of adhesion of the dressing to the wound bed, wound infection, wound healing process

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220302054168N1**

Registration date: **2022-03-03, 1400/12/12**

Registration timing: **prospective**

Last update: **2022-03-03, 1400/12/12**

Update count: **0**

Registration date

2022-03-03, 1400/12/12

Registrant information

Name

Amirali Mirfakhraei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8871 7272

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of silver-containing hydrocolloid dressings in the treatment of donor wounds of partial- thickness skin grafts

Public title

The effect of hydrocolloid dressing in the treatment of skin graft wounds

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who need partial partial- thickness skin grafts to repair skin defects for various reasons

Exclusion criteria:

Patients who do not wish to participate in the study

Patients with previously known allergies to silver

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we use the block randomization method so that after selecting patients according to the inclusion and exclusion criteria by selecting numbers from the table of random numbers and adapting to the blocks, patients are divided into study groups. To randomize the two treatment methods, we create 4 blocks in six different states, then select a number using the table of numbers, and determine the study groups by matching the numbers with the blocks. For example, if the first digit of our number is 1 to 6, select a block and the division is done, but if, for example, our number is 94071, the digit 9 is not valid and we select the next digit. Here, based on the block 4, we divide patients into groups. 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, people who are responsible for patient care and analysis of statistical data do not know about the treatment process and study groups, and information is provided to them in groups A and B

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 Sciences

Street address

Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

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Tehran

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14496145351

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**

Patients with skin defects

ICD-10 code

A66.2

ICD-10 code description

Other early skin lesions of yaws

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

The degree of adhesion of the dressing to the wound bed

Timepoint

After dressing the wound up to 14 days after dressing

Method of measurement

Standard checklist

2**Description**

Wound infection

Timepoint

After dressing the wound up to 14 days after dressing

Method of measurement

Standard checklist

Secondary outcomes**1****Description**

wound healing process
Timepoint
After dressing the wound up to 14 days after dressing
Method of measurement
Standard checklist

Intervention groups

1

Description

Intervention group: First, the partial- thickness skin grafts removed with an electric dermatome. The location of the donor, the thickness of the skin removed, and the dimensions of the skin removed are recorded for each patient. Donor injection is not performed at the donor site before removal. The donor site is then covered with epinephrine-impregnated gas at 1 in 100,000 until proper homeostasis is established. In the next step, the donor site is done with Aquacel Ag dressing made by ConvaTec company with dimensions of 15 by 15 cm or 20 by 30 cm, depending on the dimensions of the wound and according to the manufacturer's instructions, then one or two layers of dry gas are placed on this dressing and Finally, the crepe bandage is done.

Category

Treatment - Devices

2

Description

Control group: First, the partial- thickness skin grafts removed with an electric dermatome. The location of the donor, the thickness of the skin removed, and the dimensions of the skin removed are recorded for each patient. Donor injection is not performed at the donor site before removal. The donor site is then covered with epinephrine-impregnated gas at 1 in 100,000 until proper homeostasis is established. In the next step, the donor site is first placed on the wound with a gas soaked in Vaseline and then bandaged with one or two layers of dry gas and a crepe bandage.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Fatemeh Hospital

Full name of responsible person

Amir Ali Mirfakhraei

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Seyed Jamaluddin Asadabadi St. Twenty-first Street, next to Shafaq Park

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hosein Keyvani

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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 Mirfakhraei

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available