Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of skin grafts on the platelet level of patients after surgery in Imam Khomeini Hospital of Urmia in the first 6 months of 2019

Protocol summary

Study aim

The present study was conducted to evaluate the effect of skin grafts on patients' platelet counts after surgery in Imam Khomeini Teaching Hospital.

Design

This study was a quasi-experimental study with a single arm, non-randomized, own control and before and after design.

Settings and conduct

The eligible patients were selected from the burn surgical ward in Imam Khomeini Teaching Hospital in Iran. Related demographic and clinical information were collected and recorded using a checklist. Blood samples were taken from patients during surgery and on the third and fifth days after transplantation to determine the patient's platelet count. Finally, the patient's conditions were recorded regarding wound healing, vital signs, lack of sepsis criteria, platelet level, and transplant success at discharge.

Participants/Inclusion and exclusion criteria

Inclusion criteria included the consent of the patient or the patient's parents to participate in the study and patients who needed skin graft surgery. The exclusion criteria were no history of smoking, no history of diabetes, no skin infections, and not using the drugs affecting platelet factors.

Intervention groups

Eligible patients were selected and underwent skin grafting by a burn surgeon after taking blood and completing the checklist. There was no control group in this study.

Main outcome variables

The patient's platelet count was the main outcome of the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131112015390N8**
Registration date: **2024-01-06, 1402/10/16**
Registration timing: **retrospective**

Last update: **2024-01-06, 1402/10/16**
Update count: **0**

Registration date

2024-01-06, 1402/10/16

Registrant information

Name
Naser Parizad
Name of organization / entity
Urmia University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 44 1348 7649
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parizad.n@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-01, 1399/10/12

Expected recruitment end date

2021-06-30, 1400/04/09

Actual recruitment start date

2021-01-01, 1399/10/12

Actual recruitment end date

2021-06-30, 1400/04/09

Trial completion date

2021-12-29, 1400/10/08

Scientific title
Evaluation of the effect of skin grafts on the platelet level of patients after surgery in Imam Khomeini Hospital of Urmia in the first 6 months of 2019

Public title
The effect of skin grafts on the platelet level of burn patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Burn patients who needed skin graft surgery. Patients who were willing to participate in the study. Parents who consented to the participation of their minor patient.
Exclusion criteria:
Patients who had no history of smoking. Patients who had no history of diabetes. Patients who did not have skin infections. Patients who did not use drugs affecting platelet factors.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **220**
Actual sample size reached: **200**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Urmia University of Medical Sciences ethics committee
Street address
Emergency alley, Resalat Blvd., Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2020-11-22, 1399/09/02
Ethics committee reference number
IR.UMSU.REC.1399.388

Health conditions studied

1

Description of health condition studied
Burn
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The mean platelet counts
Timepoint
Blood samples were taken from patients during surgery and on the third and fifth days after transplantation to determine the patient's platelet count (Primary outcome).
Method of measurement
Sysmex KX-21N Hematology Analyzer

Secondary outcomes

empty

Intervention groups

1

Description
In patients with relatively deep or deep burns that penetrate the reticular dermis layer, blood vessels, and skin appendages, surgical debridement, and skin graft were performed to repair the burn site. For this purpose, excision and skin graft were performed in one session after the patient's initial resuscitation. In this surgical procedure, the ischemic and necrotic burnt tissue was removed layer by layer by a dermatome. Until the wound bed began to bleed, which indicated that there was blood supply from this layer and that it was not involved in a burn. After the hemostasis of bleeding, skin grafts were taken from healthy body parts that had not suffered burns. The skin grafts were taken around the thighs, and in case of the thigh's involvement, the grafts were taken from the legs, arms, forearms, and trunk. The depth of the skin removal was adjusted on the Dermatome, based on the patient’s’ need; the skin was removed on the required area, which was debrided, placed, and sutured with a stapler. At the end of the operation, the grafted area was dressed with sterile vaseline gases, and it was not opened for five days to one week. The skin that was left in place guaranteed the graft's success. The place

that suffered a deep burn was repaired by replacing the person's healthy skin (autograft).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Teaching Hospital

Full name of responsible person

Jafar Kazemzadeh

Street address

Ayat Allah Madras Blvd., Ershad Blvd., Imam Khomeini Teaching Hospital, Urmia

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81351-57157

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jafarkazemzade48@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Saber Gholizadeh

Street address

Jahad Ave., Resalat Blvd., Headquarters of Urmia University of Medical Sciences, Urmia.

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Grant name

Urmia University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Jafar Kazemzadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
Six months after the results are published

To whom data/document is available
All researchers who need data.

Under which criteria data/document could be used
All researchers who use the data for research can apply.

From where data/document is obtainable
The data will be accessible via the following email. jafarkazemzade48@gmail.com

What processes are involved for a request to access data/document
The ethics code of the current study will be sufficient for data delivery.

Comments