Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Split thickness skin graft fixation with pressure dressing and stapler fixation in burn

Protocol summary

Study aim

Determining and comparing the status of healing quality in two methods of pressure dressing and stapler

Design

This study will be conducted as a clinical trial on 30 samples. Free skin graft surgery will be performed in two burn areas by pressure dressing and stapler method and after five days, the dressings are opened and will be studied.

Settings and conduct

The present study will be conducted in the burn department and operating room of Imam Khomeini (RA) hospital in Ardabil. People will be included in the study according to the inclusion criteria, and free skin grafting surgery will be performed in two burn areas using pressure dressing and stapler method, and after five days, the dressings will be opened and grips of the two The area in terms of necrosis, infection, displacement, and finally got the appropriate quality (based on the examination and judgment of the surgeon) will be recorded in two areas of the studied burn.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with 2nd and 3rd degree burns 2. Patients in the age range of 30-60 years 3. Not taking immunosuppressive drugs 4. Not suffering from underlying diseases (diabetes, chronic Renal failure, etc.) 5. Absence of addiction and heavy consumption of tobacco 6. Taking informed consent Non-entry criteria: 1.A burn with an extent of more than 50% that it is not possible to remove the healthy skin as a scar

Intervention groups

Free skin grafting surgery will be performed in two burn areas using pressure dressing and stapler method, and after five days, the dressings will be opened and the grafts in the two areas will be moved in terms of necrosis, infection, and finally it will be of good quality (according to the examination). and the surgeon's judgment (will be studied in two areas of burn).

Main outcome variables

Necrosis, infection, displacement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100628004256N9**
Registration date: **2023-05-15, 1402/02/25**
Registration timing: **prospective**

Last update: **2023-05-15, 1402/02/25**
Update count: **0**

Registration date

2023-05-15, 1402/02/25

Registrant information

Name

Nasrin Samadi

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 1551 3057

Email address

na.samadi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-20, 1402/03/30

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Split thickness skin graft fixation with pressure dressing and stapler fixation in burn

Public title
Comparison of pressure dressing and stapler in skin graft
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with 2nd and 3rd degree burns Patients in the age range of 30-60 years Not taking immunosuppressive drugs No underlying diseases (diabetes, chronic Renal failure, etc.) No addiction and heavy smoking obtaining informed consent
Exclusion criteria:
A burn with an extent of more than 50% that it is not possible to remove the healthy skin as a scar
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
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
Research Ethic Committees of Ardabil University of Medical Sciences
Street address
Daneshgah st
City
Ardabil
Province
Ardabil
Postal code
۵۶۱۸۹-۸۵۹۹۱
Approval date
2023-01-21, 1401/11/01
Ethics committee reference number
IR.ARUMS.REC.1401.216

Health conditions studied

1

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

Primary outcomes

1

Description
Skin graft in terms of necrosis
Timepoint
During surgery, 5 and 7 days after graft
Method of measurement
The grafts of two areas will be studied in terms of necrosis, and finally the quality of scars (based on the examination and judgment of the surgeon) in the two areas of the burn.

2

Description
Skin graft in terms of infection
Timepoint
During surgery, 5 and 7 days after graft
Method of measurement
The grafts of two areas will be studied in terms of infection, and finally the quality of scars (based on the examination and judgment of the surgeon) in the two areas of the burn.

3

Description
Skin graft in terms of necrosis
Timepoint
During surgery, 5 and 7 days after graft
Method of measurement
The grafts of two areas will be studied in terms of displacement and finally the quality of the grips (based on the examination and judgment of the surgeon) in the two regions of the burn.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Free skin grafting surgery will be performed in two burn areas using pressure dressing and stapler method, and after five days, the dressings will be opened and according to the regulatory questionnaire, the two areas will be affected in terms of necrosis, infection, and displacement. It was taken and finally the quality was taken (based on the surgeon's examination and judgment) in two areas of the studied burn.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Ardabil

Full name of responsible person

Dr Hamed Mohammadi

Street address

Daneshgah st

City

Ardabil

Province

Ardabil

Postal code

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Phone

+98 914 682 9709

Email

na.samadi@arums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Hamed Mohammadi

Street address

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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

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Hamed Mohammadi

Position

surgeon

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Daneshgah st

City

Ardabil

Province

Ardabil

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Person responsible for updating data

Contact

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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