Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Sep 2026

Evaluation of the effect of overlapping wound edges with skin graft in reducing hypertrophic scar formation

Protocol summary

Study aim
Evaluation of the effect of overlapping wound edges with skin graft in reducing hypertrophic scar formation

Design
A clinical trial with a control group, with parallel groups, unblinded, randomized, on 74 patients. The block method will be used for randomization.

Settings and conduct
A study in Imam Reza Birjand Hospital, South Khorasan province, on 74 patients who were divided into two groups of two skin graft methods in a simple random manner. Patients are evaluated at the beginning of the study, 1 and 6 months after the start of the study

Participants/Inclusion and exclusion criteria
Patients admitted to the burn department of Imam Reza Birjand Hospital, who are candidates for graft transplantation, were included in the study in 2023. Inclusion criteria: 2nd and 3rd degree burns, patient consent to enter the study and exclusion criteria: pregnancy, history of chemotherapy, diabetes, substance abuse and receiving systemic drugs such as glucocorticosteroids.

Intervention groups
Burn patients are included in the study. The suitable donor site for the graft is selected by the plastic surgery specialist based on the burn area, thickness and color of the donor site. A skin graft with a thickness of 0.4-0.6 mm will be removed using a rechargeable dermatome and will be transferred to the intended burn site and grafted. The burn sites of the patients are randomly divided into two overlapping techniques and equal to the edges of the wound. In the matching technique with the edges of the burn wound, the area of the harvested tissue is exactly equal to the edges of the wound in the desired location. In the overlapping technique with a margin of 2 mm on each side, repair and grafting is done for patients. Staples are then removed 5 to 10 days after surgery. The preventive treatment of scar compression garments is prescribed for wounds in the same way.

Main outcome variables
Burn scar pain

General information

Reason for update

Acronym
همپوشانی لبه های زخم با گرافت جلدی در کاهش ایجاد اسکار

IRCT registration information
IRCT registration number: **IRCT20190618043934N22**
Registration date: **2023-10-14, 1402/07/22**
Registration timing: **prospective**

Last update: **2023-10-14, 1402/07/22**
Update count: **0**

Registration date
2023-10-14, 1402/07/22

Registrant information

Name
Zabihullah Mohaghegh

Name of organization / entity

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Iran (Islamic Republic of)

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Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2023-12-22, 1402/10/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of overlapping wound edges with skin graft in reducing hypertrophic scar formation

Public title

Evaluation of the effect of overlapping wound edges with skin graft in reducing hypertrophic scar formation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

2nd and 3rd degree burns Patient consent to enter the study

Exclusion criteria:

pregnancy History of chemotherapy diabetes Drug abuse Receiving systemic medications such as glucocorticosteroids

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients in two areas of the total number of burns in the body of patients who are similar in terms of percentage of burns will be selected and will be repaired by two graft methods: 1. Overlapping and 2. Equal to the edges of the burn wound. The selection of the site and repair method is simple random and in a blocked method inside a closed and sealed envelope, which includes the burn site and repair with a graft using the overlapping method (A) or a burn site with a graft using the same method as the edges of the burn wound (A). B) is divided. In this way, various quadruple blocks were created first (AABB, BBAA, ABAB, BABA, ABBA and BABA). One of these blocks is randomly selected and the patients are divided into one of two groups A or B. Then randomization is done for other patients as well.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand Town

City

Birjand

Province

South Khorasan

Postal code

9717811674

Approval date

2022-02-28, 1400/12/09

Ethics committee reference number

IR.BUMS.REC.1400.403

Health conditions studied

1

Description of health condition studied

burn

ICD-10 code

M61.3

ICD-10 code description

Calcification and ossification of muscles associated with burns

Primary outcomes

1

Description

Pain

Timepoint

The beginning of the study, 1 month and 6 months after the start of the study

Method of measurement

Using a visual pain scale

2

Description

Burn scar

Timepoint

The beginning of the study, 1 month and 6 months after the start of the study

Method of measurement

Using the Vancouver scar scale including four vascular indices, flexibility, pigmentation and the height of the wound edges are evaluated.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group 1, patients hospitalized in the burn department, candidates for graft transplantation, Imam Reza Birjand Hospital, where the burn site and repair with graft will be done by overlapping method.
Category
Treatment - Surgery

2

Description
Intervention group: Intervention group 2 patients admitted to the burn ward of Imam Reza Birjand Hospital, who are candidates for graft transplantation, where the burn site will be treated with a graft in the same way as the edges of the burn wound.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital-Birjand
Full name of responsible person
Dr Abdollah Adib
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Birjand 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
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Full name of responsible person
Zabihullah Mohaghegh
Position
Student
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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