

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3232 3232

##### Email address

oabstudent@gmail.com

##### 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

##### Street address

School of Medicine, Birjand University of medical sciences, Ghahhari Blvd,

##### City

Birjand

##### Province

South Khorasan

##### Postal code

9717964151

##### Phone

+98 56 3232 3232

##### Email

public\_r@bums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Birjand University of Medical Sciences

##### Full name of responsible person

Dr masoud Yousefi

##### 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

#### Phone

+98 56 3238 1200

#### Email

research@bums.ac.ir

#### 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

Birjand University of Medical Sciences

##### Full name of responsible person

Zabihullah Mohaghegh

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

General Practitioner

##### Street address

School of Medicine, Birjand University of medical sciences, Ghahhari Blvd, Birjand Town

##### City

Birjand

##### Province

South Khorasan

##### Postal code

9717934888

##### Phone

+98 56 3232 3232

##### Email

zabihullahmohaghegh@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Birjand University of Medical Sciences

##### Full name of responsible person

Dr Mahdi Ghoncheh

**Position**

Member of the Faculty

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

**Street address**

Department of Surgery, School of Medicine, Birjand  
University of medical sciences, Ghahhari Blvd, Birjand  
Town

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717811674

**Phone**

+98 56 3232 3232

**Email**

mahdighoncheh@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Zabihullah Mohaghegh

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

General Practitioner

**Street address**

School of Medicine, Birjand University of medical  
sciences, Ghahhari Blvd, Birjand Town

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717934888

**Phone**

+98 56 3232 3232

**Email**

zabihullahmohaghegh@gmail.com

**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