

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Performing partial thickness skin graft from a flap of skin to repair defects resulting from the same flap in leg in patients with complex ulcers: a clinical trial

#### Protocol summary

##### Summary

Objectives: To determine performance of partial thickness skin graft from a flap of skin to repair defects resulting from the same flap in leg in patients with complex ulcers Design: a clinical trial. Setting and conduct: The eligible patients with complex ulcers who are candidate for skin graft and will refer to Besat Hospital during the study period will be enrolled into the trial. Inclusion criteria: complex ulcers with indication of skin graft. Exclusion criteria: inability to prepare skin graft. Intervention group: Providing a thickness of 3 mm from the flap of skin graft to repair the defect resulting from the same flap of skin in legs. Control group: without control group. Primary outcome: Graft success on the fifth day after surgery through clinical examination. Secondary outcome: (a) the patient satisfaction on the fifth day after surgery using standard questionnaire; (b) the severity of pain on the fifth day and the second week after surgery using a visual analog scale. Randomization: This study has an intervention group without control group, therefore it is without randomization. Blinding: Not possible.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201611069014N132**  
Registration date: **2016-11-09, 1395/08/19**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-11-09, 1395/08/19

##### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for Research the Technology, Hamadan  
University of Medical Sciences

##### Expected recruitment start date

2015-06-22, 1394/04/01

##### Expected recruitment end date

2016-06-22, 1395/04/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Performing partial thickness skin graft from a flap of skin to repair defects resulting from the same flap in leg in patients with complex ulcers: a clinical trial

##### Public title

Performing partial thickness skin graft from a flap of skin to repair defects resulting from the same flap in leg in patients with complex ulcers

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: complex ulcers with indication of skin graft. Exclusion criteria: inability to prepare skin graft.

## Age

No age limit

## Gender

Both

## Phase

1-2

## Groups that have been masked

No information

## Sample size

Target sample size: 20

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

Randomization: This study has an intervention group without control group, therefore it is without randomization. Blinding: Not possible.

## Secondary Ids

### 1

#### Registry name

the patient satisfaction

#### Secondary trial Id

on the fifth day after surgery

#### Registration date

empty

### 2

#### Registry name

the severity of pain

#### Secondary trial Id

on the fifth day and the second week after surgery

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### City

Hamadan

#### Postal code

6517838695

#### Approval date

2015-06-20, 1394/03/30

#### Ethics committee reference number

IR.UMSHA.REC.1394.154

## Health conditions studied

### 1

#### Description of health condition studied

complex ulcers

#### ICD-10 code

L98.4

#### ICD-10 code description

Chronic ulcer of skin, not elsewhere classified

## Primary outcomes

### 1

#### Description

Graft success

#### Timepoint

on the fifth day after surgery

#### Method of measurement

through clinical examination

## Secondary outcomes

### 1

#### Description

the patient satisfaction

#### Timepoint

on the fifth day after surgery

#### Method of measurement

using standard questionnaire

### 2

#### Description

the severity of pain

#### Timepoint

on the fifth day and the second week after surgery

#### Method of measurement

using a visual analog scale

## Intervention groups

### 1

#### Description

Intervention group: Providing a thickness of 3 mm from the flap of skin graft to repair the defect resulting from the same flap of skin in legs.

#### Category

Treatment - Surgery

## 2

### Description

Control group: without control group.

### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat Hospital

##### Full name of responsible person

Yadollah Raeisi Makiani

##### Street address

Besat Hospital, Shahed Square

##### City

Hamadan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences

##### Full name of responsible person

Dr Saeid Bashirian

##### Street address

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### City

Hamadan

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice-chancellor for Research the Technology, Hamadan  
University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Besat Hospital

#### Full name of responsible person

Yadollah Raeisi Makiani

#### Position

Resident of Surgery

#### Other areas of specialty/work

#### Street address

Besat Hospital, Shahed Square

#### City

Hamadan

#### Postal code

#### Phone

+98 81 3364 0030

#### Fax

#### Email

dr.raissi@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Besat Hospital

#### Full name of responsible person

Dr Mahdi Eskandarloo

#### Position

Surgeon

#### Other areas of specialty/work

#### Street address

Besat Hospital, Shahed Square

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+98 81 3364 0030

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dr.escandarlou@gmail.com

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Department of Epidemiology

#### Full name of responsible person

Dr Jalal Poorolajal

#### Position

Associate Professor

#### Other areas of specialty/work

#### Street address

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

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6517838695

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#### Fax

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poorolajal@umsha.ac.ir

#### Web page address

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*