

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

City

Hamadan

Postal code

Phone

+98 81 3364 0030

Fax

Email

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

City

Hamadan

Postal code

6517838695

Phone

+81 38380090

Fax

Email

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