

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the outcomes and complications of pedicle cutaneous flap versus standard cutaneous flap in patients with complicated wound in lower extremity: a randomized clinical trial

Protocol summary

Summary

Objectives: To compare the outcomes and complications of pedicle cutaneous flaps versus standard cutaneous flaps in patients with complicated wound in lower extremity. Design: A randomized clinical trial. Setting and conduct: The eligible patients who with complicated wound in lower extremity will refer to Besat Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 65 years; complicated wound in lower extremity Exclusion criteria: Vascular dysfunction in the lower extremity; presence of a wound or skin disease in the location of the flap. Intervention group: Surgical repair of the complicated wound using a pedicle cutaneous flap. Control group: Surgical repair of the complicated wound using a standard cutaneous flap. Primary outcome: Success of the skin graft 35 days and 3 months after surgery through physical examination. Secondary outcome: Post-surgical pain on the first to fifth days after surgery using visual analog scale. Randomization: Random assignment of the patients to the intervention and control groups using block randomization. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707229014N175**
Registration date: **2017-07-27, 1396/05/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-27, 1396/05/05

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2017-02-28, 1395/12/10

Expected recruitment end date

2017-09-01, 1396/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the outcomes and complications of pedicle cutaneous flap versus standard cutaneous flap in patients with complicated wound in lower extremity: a randomized clinical trial

Public title

Comparison of the outcomes and complications of pedicle cutaneous flap versus standard cutaneous flap in patients with complicated wound in lower extremity

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: Age of 18 to 65 years; complicated wound in lower extremity
 Exclusion criteria: Vascular dysfunction in the lower extremity; presence of a wound or skin disease in the location of the flap.

Age
 From **18 years** old to **65 years** old

Gender
 Both

Phase
 2

Groups that have been masked
No information

Sample size
 Target sample size: **40**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features
 Randomization: Random assignment of the patients to the intervention and control groups using block randomization. Blinding: Not possible.

Secondary Ids

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

Approval date

2017-02-18, 1395/11/30

Ethics committee reference number

IR.UMSHA.REC.1395.542

Health conditions studied

1

Description of health condition studied

complicated wound in lower extremity

ICD-10 code

T13.1

ICD-10 code description

Open wound of lower limb, level unspecified

Primary outcomes

1

Description

Success of the skin graft

Timepoint

35 days and 3 months after surgery

Method of measurement

through physical examination

Secondary outcomes

1

Description

Post-surgical pain

Timepoint

on the first to fifth days after surgery

Method of measurement

using visual analog scale

Intervention groups

1

Description

Intervention group: Surgical repair of the complicated wound using a pedicle cutaneous flap.

Category

Treatment - Surgery

2

Description

Control group: Surgical repair of the complicated wound using a standard cutaneous flap.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Mahdi Eskandarlou

Street address

Besat Hospital, Shahed Square

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research and 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 and 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

Dr Mahdi Eskandarlou

Position

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Other areas of specialty/work

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Person responsible for updating data

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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