

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Additive effect of Ilizarov frame application to routine wound care in reducing postoperative complications among patients with lower limb injury candidates for reverse flap surgery

Protocol summary

Study aim

Comparison of surgical flap postoperative results with distal base (reverse sural) in two groups of patients with Ilizarov offloading and without Ilizarov offloading

Design

This clinical trial will be done on 20 patients (one intervention group consists of 10 patients and the control group is parallel to 10 patients). Randomization is done by the blocking randomization method.

Settings and conduct

Patients with extensive lower limb injuries referred to Shohada Tajrish Hospital in Tehran candidates for reverse sural flap will be randomly assigned to two groups of control and intervention. Due to the patient's knowledge of the device embedded in his limb after surgery in the intervention group, blinding is not performed in this study.

Participants/Inclusion and exclusion criteria

Patients above 18 years with extensive lower limb injury, candidates for reverse sural flap surgery will be included in the study, and patients with lower limb injuries concurrent with neurovascular injuries for whom flap surgery is not possible will be excluded.

Intervention groups

Patients in the experimental group will be followed after flap surgery, the wound dressing will be vaselinated sterile gauze on which sterile gas is placed above and closed with a cotton band, which for better maintenance of the flap (skin graft) must be lying prone or lateral. In addition to Vaseline and sterile gauze dressing, patients in the intervention group will have an Ilizarov offloading device, and due to having this device, they can lie supine after surgery.

Main outcome variables

The postoperative volume of bleeding, the rate of infection and wound problems of the patient, and the amount of flap congestion will be assessed

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211201053235N3**

Registration date: **2022-04-15, 1401/01/26**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-15, 1401/01/26**

Update count: **0**

Registration date

2022-04-15, 1401/01/26

Registrant information

Name

Meisam Jafari Kafiabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8000

Email address

dr.jafari8567@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Additive effect of Ilizarov frame application to routine wound care in reducing postoperative complications among patients with lower limb injury candidates for reverse flap surgery

Public title

Ilizarov frame in flap postoperative care

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients above 18 years with extensive lower limb injury candidate for reverse flap surgery patients with lower limb injuries whose vessels are intact and the distal arterial-arterial connections are patent

Exclusion criteria:

Patients with vascular injuries of the lower extremities whose blood flow is impaired Patients with neural injuries

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of blocks is done by dividing the included patients into blocks with multiples of 2 (2, 4, 6, 8, etc.), then randomization of patients in each block is done in such a way that half of the patients are assigned to the experimental group and the other half to the control. Then we will choose the blocks randomly. This method ensures equal treatment allocation within each block when the complete block is used.

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 Shahid Beheshti University of Medical Sciences

Street address

Iran, Tehran Velenjak St. , Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

198353-5511

Approval date

2022-02-06, 1400/11/17

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.1012

Health conditions studied**1****Description of health condition studied**

Other specified diseases of the skin (complications of free flaps)

ICD-10 code

EM0Y

ICD-10 code description

Other specified diseases of the skin

Primary outcomes**1****Description**

The rate of infection after surgery

Timepoint

At 2 weeks, 4 weeks, 6 weeks, 8 weeks, 3 months and 6 months after surgery

Method of measurement

Examination of wounds for infection

Secondary outcomes**1****Description**

Flap congestion after surgery

Timepoint

At 2 weeks, 4 weeks, 6 weeks, 8 weeks, 3 months and 6 months after surgery

Method of measurement

Physical examination and observation of wound by surgeon

2**Description**

Bleeding rate after surgery

Timepoint

At 2 weeks, 4 weeks, 6 weeks, 8 weeks, 3 months and 6 months after surgery

Method of measurement

Physical examination of the patient and assessing the volume of blood drawn from the patient's drain

Intervention groups

1

Description

Intervention group: 10 patients with severe lower limb injuries who are candidates for flap surgery will have an Ilizarov implanted after the flap surgery.

Category

Treatment - Surgery

2

Description

Control group: 10 patients with severe lower limb injuries who are candidates for flap surgery will be followed up after flap surgery without implanting an Ilizarov device and according to the routine surgical wound care protocol.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Meisam Jafari Kafiabadi

Street address

Shohada Tajrish Hospital, Tajrish square

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

pr_shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Bldg No.2, Shahid Beheshti university of medical sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 2243 9770

Email

intl_office@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farsad Biglari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Tajrish square, Tehran

City

Tehran

Province

Tehran

Postal code

1989934148.

Phone

+98 21 25719

Email

pr_shohada@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Meisam Jafari Kafiabadi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Tajrish square

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

dr.jafari8567@yahoo.com

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Meisam Jafari Kafiabadi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Tajrish square

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

dr.jafari8567@yahoo.com

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Participants' data file, study protocol, statistical analysis map, informed consent form and clinical study report will all be fully shareable after disclosing personal information.

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

The information will be available to anyone who requests access

Under which criteria data/document could be used

Data are provided to study the study process or use in systematic review studies and meta-analysis.

From where data/document is obtainable

Meisam Jafari Kafiabadi, Email:dr.jafari8567@yahoo.com, Address: School of Medicine ,Shahid Beheshti University of Medical Sciences, Yemen St., Shahid Chamran Highway, Tehran ,Iran Postal Code: 1985717443

What processes are involved for a request to access data/document

After sending the request for access to information and specifying the type of requested information to the email of the person in charge of correspondence, they will prepare the requested information and send it to the applicant.

Comments