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
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Iran (Islamic Republic of)
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+98 21 2271 8000
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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
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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.
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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