

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The efficacy of face-to-face training with a surgeon versus virtual instruction on the outcome of reverse sural flap surgery

Protocol summary

Study aim

The efficacy of face-to-face training with a surgeon versus virtual instruction on the outcome of reverse sural flap surgery

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. 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 intervention group were trained in face to face before flap surgery, but in the intervention group patients were shown short videos.

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: **IRCT20211201053235N5**

Registration date: **2022-06-18, 1401/03/28**

Registration timing: **prospective**

Last update: **2022-06-18, 1401/03/28**

Update count: **0**

Registration date

2022-06-18, 1401/03/28

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

2022-06-22, 1401/04/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of face-to-face training with a surgeon versus virtual instruction on the outcome of reverse sural flap surgery

Public title

The efficacy of virtual instruction on the outcome of reverse sural flap surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
 Patients above 18 years extensive lower limb injury candidate for reverse flap surgery patients with lower limb injuries whose vessels are intact 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 of lower extremities

Age
 From **18 years** old

Gender
 Both

Phase
 2

Groups that have been masked
No information

Sample size
 Target sample size: **30**

Randomization (investigator's opinion)
 Not randomized

Randomization description

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

Shahrdari Street, Tajrish Square

City

tehran

Province

Tehran

Postal code

198353-5511

Approval date

2022-03-13, 1400/12/22

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.1195

Health conditions studied

1

Description of health condition studied

Crushing injury of lower leg

ICD-10 code

S87

ICD-10 code description

Crushing injury of lower leg

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

2

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

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Fifteen patients with severe lower limb injuries who are candidates for reverse sural flap surgery, the video is shown to them several times before surgery, and before surgery, we make sure that the patient sees and understands the video.

Category

Rehabilitation

2

Description

Control group: In the control group, the surgeon explains to the patient face to face. The other pre-and post-operative consideration is similar and all surgeries are performed by one surgeon.

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
Tajrish Square, Shahr-dari Street
City
tehran
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Postal code
1989934148
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+98 21 25719
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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
Tajrish Square, Shahr-dari Street
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19839-63113
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intl_office@sbmu.ac.ir

Grant name

Grant code / Reference number

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

No

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
Medical doctor
Other areas of specialty/work
Orthopedics
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

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

The information will be available to anyone who requests access

From where data/document is obtainable

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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