

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of leg elevation on prevention of leg pain and edema and anxiety among patients undergoing coronary artery bypass grafting

Protocol summary

Summary

Objectives: The effect of leg elevation on prevention of leg pain and edema and anxiety among patients undergoing coronary artery bypass grafting. **Design:** This study is a randomized controlled clinical trial on patients undergoing CABG. In order to compare the average scores of edema pain and anxiety in the intervention group and the control group. Samples will be selected from all patients undergoing CABG hospital admission. After a preliminary study to determine the sample size and the justification of eligible patients, purpose of the study will be explained to patients. After preparing the list of the day after operation candidates, researcher will go to ward (between the hours 17-19) to fill the questionnaires. **Participants:** Patients undergoing CABG. **Intervention:** The samples using random numbers table will be divided into two groups. Leg elevating Intervention will begin after surgery in the ICU and will continue to operation ward. We will put pillow under leg that is graft donor. If only one leg is vein donor the leg elevation will be done by putting pillow under foot and if both feet are vein donor, raising the foot of the bed to 30 degrees will be carried out. The control group will receive no intervention. Recollecting data related for pain, anxiety and edema in discharging from the ICU and discharging from ward will be carried out by research assistant in both groups. **Main outcome measures variables:** Demographic Spielberger State Anxiety Scale and Visual Analogue Scale and the incidence of Edema.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051412264N3**

Registration date: **2016-12-03, 1395/09/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-03, 1395/09/13

Registrant information

Name

Farahnaz Abdollahzadeh

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2016-07-19, 1395/04/29

Expected recruitment end date

2016-11-19, 1395/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of leg elevation on prevention of leg pain and edema and anxiety among patients undergoing coronary artery bypass grafting

Public title

The effect of leg elevation on prevention of leg pain and edema and anxiety among patients undergoing coronary

artery bypass grafting

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: patients undergoing coronary artery bypass grafting; The ability to read and write to complete the anxiety questionnaire; age (between 18 and 70 years); Lack of movement problems; The absence of an underlying disease such as renal failure, congestive heart failure, deep vein thrombosis, absence of edema and varicose veins in the lower extremities, lack of oral contraceptive drugs
Exclusion criteria: pulmonary embolism; immobility before surgery; Cancel patients to participate in research

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization: The samples using random numbers table will be divided into two groups.

Secondary Ids

1

Registry name
Secondary trial Id
Registration date
2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee in Tabriz University of Medical Sciences
Street address
Tabriz university of medical sciences; Golgasht Avenue.
City
Tabriz
Postal code

5138947977

Approval date
2016-06-08, 1395/03/19
Ethics committee reference number
IR.TBZMED.REC.1395.202

Health conditions studied

1

Description of health condition studied
Patients undergoing coronary artery bypass grafting
ICD-10 code
I97.1
ICD-10 code description
following cardiac surgery or due to presence of cardiac prosthesis

Primary outcomes

1

Description
Anxiety
Timepoint
The day before surgery, discharge from ICU, discharge from the public sector
Method of measurement
Spielberger questionnaire

2

Description
Leg edema
Timepoint
The day before surgery, discharge from ICU, discharge from the public sector
Method of measurement
Centimeter

3

Description
Leg pain
Timepoint
The day before surgery, discharge from ICU, discharge from the public sector
Method of measurement
VAS Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Leg elevation Intervention will be done after surgery and in the ICU and will be continued in operation ward. It will take place on the Foot that is

graft donor. If only one leg is vein donor, leg elevation will be done by putting pillows under foot and if both feet are vein donor, leg elevation will be done by bringing up the head part of bed about 30 degrees .

Category

Other

2

Description

Control group: The control group will receive no intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital

Full name of responsible person

Ms. Roghayeh Pourali

Street address

University Avenue, Shahid Madani Hospital

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person

Doctor Mohammad Reza Rashidi

Street address

Tabriz University of Medical Sciences, Golgasht Avenue. Tabriz

City

Tabriz

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 of Tabriz 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

Kosar Dormitory, Shariati Avenue. Tabriz

Full name of responsible person

Farahnaz Abdollahzadeh

Position

Masters of Sciences

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Rougayeh Pourali

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Masters of Sciences Student

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-

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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