

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### **Predictive effect of central venous pressure changes from passive leg elevation in homodynamic stability during anesthesia induction in adult cardiac surgery**

#### **Protocol summary**

##### **Summary**

Objective: Studying the predictive effect of central venous pressure changes from passive leg elevation in homodynamic stability during anesthesia induction in adult cardiac surgery Design: Prospective randomized clinical trial Setting and conduct: One hundred and twenty adult patients candidate for elective cardiac surgery, randomly will be allocated in two study and control groups (N=60). Using local anesthesia, arterial and central venous catheters placed and invasive arterial and central venous blood pressures will be monitored. Anesthesia will be induced using fentanyl, midazolam and cisatracurium. In study group patients, passive leg elevation (30-45 degrees) maneuver will performed one minute before anesthesia induction and got back to normal position, 12-15 minutes later. In control group anesthesia induction is performed in supine position. Invasive arterial and central venous pressures will be recorded one minute before and after induction, 5, 10 and 20 minutes after tracheal intubation. Hypotension below 100 mmHg will be treated using ephedrine 10 mg. At the end the arterial and central venous blood pressures changes within and between groups will be compared and predictive effect of central venous blood pressures changes after passive leg elevation maneuver on homodynamic stability will be calculated. Inclusion criteria: Patients between 18-70 Years olds who are candidate for elective cardiac surgery Exclusion criteria: Urgent surgery; redo surgery; non-cardiac disease (diabetes, hepatic and renal); Left Ventricular EF less than 40 percent; recent acute MI or unstable angina; systolic arterial blood pressures more than 160 mmHg Intervention: Passive leg elevation maneuver before anesthesia induction Outcome measures: Arterial and central venous blood pressures changes

#### **General information**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT201410111127N4**

Registration date: **2014-10-18, 1393/07/26**

Registration timing: **prospective**

Last update:

Update count: **0**

##### **Registration date**

2014-10-18, 1393/07/26

##### **Registrant information**

##### **Name**

Eissa Bilehjani

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 41 3329 6124

##### **Email address**

bilehjanii@tbzmed.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

Vice Chancellor for Research of Tabriz University of Medical Sciences

##### **Expected recruitment start date**

2014-11-20, 1393/08/29

##### **Expected recruitment end date**

2015-08-20, 1394/05/29

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Predictive effect of central venous pressure changes from passive leg elevation in homodynamic stability during anesthesia induction in adult cardiac surgery

**Public title**

Predictive effect of central venous pressure changes from passive leg elevation in homodynamic stability during anesthesia induction in adult cardiac surgery

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Patients between 18-70 Years olds who are candidate for elective cardiac surgery Exclusion criteria: Urgent surgery; redo surgery; non-cardiac disease (diabetes, hepatic and renal); Left Ventricular EF less than 40 percent; recent acute MI or unstable angina; systolic arterial blood pressures more than 160 mmHg

**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: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tabriz University of Medical Sciences

**Street address**

Golgasht, Daneshgah Street, Tabriz

**City**

Tabriz

**Postal code****Approval date**

2013-10-19, 1392/07/27

**Ethics committee reference number**

92215

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

Drug induced hypotension in anesthesia induction

**ICD-10 code**

I95.2

**ICD-10 code description**

Hypotension due to drugs

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

Central venous blood pressure changes after passive leg elevation maneuver

**Timepoint**

One, five, ten and twenty minutes after 5, 10 and 20 minutes after tracheal intubation

**Method of measurement**

Invasive central venous blood pressures measurement using electronic monitor

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

Arterial blood pressure changes after passive leg elevation maneuver

**Timepoint**

One, five, ten and twenty minutes after 5, 10 and 20 minutes after tracheal intubation

**Method of measurement**

Invasive arterial venous blood pressures measurement using electronic monitor

**Intervention groups****1****Description**

Intervention group: Passive leg elevation maneuver before anesthesia induction

**Category**

Treatment - Other

**2****Description**

Control group: Anesthesia induction in supine position

**Category**

Other

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Madani Heart Hospital

**Full name of responsible person**

Eissa Bilehjani

**Street address**

Madani Heart Center, Daneshgah Street, Tabriz

**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**

Mohammad Reza Rashidi

**Street address**

Tabriz University of Medical Sciences, Daneshgah Street, 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**

Medicine faculty, Tabriz University of Medical Sciences

**Full name of responsible person**

Hassan Soleiman Pour

**Position**

Vice Chancellor for research of Tabriz University of Medical Sciences

**Other areas of specialty/work****Street address**

Tabriz Medicine faculty, Daneshgah Street, Tabriz

**City**

Tabriz

**Postal code****Phone**

+98 41 3336 4667

**Fax****Email**

soleimanpourh@tbzmed.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Solmaz Fakhari

**Position**

Assistant Professor in Anesthesiology

**Other areas of specialty/work****Street address**

Madani Heart Center, Daneshgah Street, Tabriz

**City**

Tabriz

**Postal code**

5166615573

**Phone**

+98 41 3337 3950

**Fax**

+98 41 3337 3950

**Email**

solmaz\_fakhari@yahoo.com, fakhariso@tbzmed.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Eissa Bilehjani

**Position**

Assistant Professor in Anesthesiology

**Other areas of specialty/work****Street address**

Madani Heart Center, Daneshgah Street, Tabriz

**City**

Tabriz

**Postal code**

5166615573

**Phone**

+98 41 3337 3950

**Fax**

+98 41 3337 3950

**Email**

bilehjani@tbzmed.ac.ir; isa\_bilehjani@yahoo.com; isadavod@gmail.com

**Web page address**

## 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*