

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Infusion of low dose of vasopressin versus phenylephrine for prevention of cardiopulmonary bypass induced vasoplegic syndrome in patients undergoing

#### Protocol summary

##### Summary

Objective: Studying the effect of vasopressin in preventing vasoplegic shock from cardiopulmonary bypass Design: Prospective randomized clinical trial Setting and conduct: Seventy five adult patients candidate for elective cardiac surgery using cardiopulmonary bypass (CPB), randomly will be allocated in three vasopressin, phenylephrine and placebo groups (N=25). Anesthesia induction and maintenance will be done using intravenous midazolam, fentanyl and cisatracurium. With starting CPB infusion of vasopressin (0.1 IU/min), phenylephrine (0.1 µg/kg/min) or normal saline (2 ml/h) was started in Vasopressin, Phenylephrine and placebo groups, respectively and continued up to 4 hours after weaning from CPB. Patients hemodynamic were managed using appropriate vasodilator or vasoconstrictor (Mean arterial blood pressure 60-80 mmHg during CPB and systolic pressure 100-120 mmHg after CPB). Inclusion criteria: All patients 18 up to 70 years olds who are candidate for elective cardiac surgery using cardiopulmonary bypass Exclusion Criteria: Urgent Surgery; Surgery without cardiopulmonary bypass; Diabetes mellitus; Respiratory, hepatic or renal disease Intervention: Starting infusion of vasopressin 0.1 IU/min or phenylephrine (0.1 µg/kg/min) with starting of cardiopulmonary bypass in vasopressin and phenylephrine groups, respectively and continuing it up to 4 hours after weaning from CPB. Outcome measures: Needs to vasoactive drugs and postoperative complications

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201408201127N2**  
Registration date: **2014-10-18, 1393/07/26**

Registration timing: **registered\_while\_recruiting**

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

bilehjani@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2014-09-23, 1393/07/01

##### Expected recruitment end date

2015-03-18, 1393/12/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Infusion of low dose of vasopressin versus phenylephrine for prevention of cardiopulmonary bypass induced vasoplegic syndrome in patients undergoing

## Public title

Infusion of low dose of vasopressin versus phenylephrine for prevention of cardiopulmonary bypass induced vasoplegic syndrome in patients undergoing coronary artery bypass grafting surgery

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: Patients 18 up to 70 years olds who are candidate for elective cardiac surgery using cardiopulmonary bypass Exclusion Criteria: Urgent Surgery; Surgery without cardiopulmonary bypass; Diabetes mellitus; Respiratory, hepatic or renal disease

## Age

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

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **75**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

Using stratified permuted block randomization method, 75 patients will be allocated in three vasopressin, phenylephrine and placebo groups (N=25).

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Sciences Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Golgasht, Daneshgah Street, Tabriz

##### City

Tabriz

##### Postal code

#### Approval date

2011-08-20, 1390/05/29

#### Ethics committee reference number

9266

## Health conditions studied

### 1

#### Description of health condition studied

Cardiopulmonary bypass induced vasoplegic shock

#### ICD-10 code

I70-I79

#### ICD-10 code description

Diseases of arteries, arterioles and capillaries

## Primary outcomes

### 1

#### Description

severity of post operative vasoplegic shock

#### Timepoint

post cardiopulmonary bypass and post operative period

#### Method of measurement

Needs to vasoactive drugs

## Secondary outcomes

### 1

#### Description

Post operative complications

#### Timepoint

Post operatively in intensive care unite

#### Method of measurement

Clinical evaluation

## Intervention groups

### 1

#### Description

Intervention group1: Starting infusion of vasopressin (Exir pharmaceutical co. Iran) 0.1 IU/min with starting of cardiopulmonary bypass and continuing it up to 4 hours after weaning from cardiopulmonary bypass.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group2: Starting infusion of phenylephrine (West-ward Pharmaceutical Corp. USA) 0.1 µg/kg/min (prepared as 5 mg in 50 ml normal saline) with starting of cardiopulmonary bypass and continuing it up to 4 hours after weaning from cardiopulmonary bypass.

#### Category

Treatment - Drugs

### 3

#### Description

Placebo group: Starting NaCl 0.9% Infusion (2 ml/h) with starting of cardiopulmonary bypass and continuing it up to 4 hours after weaning from cardiopulmonary bypass.

**Category**  
Placebo

## 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**

Madani Heart Center, 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**

516615573

**Phone**

+98 41 3337 3950

**Fax**

+98 41 3337 3950

**Email**

solmaz\_fakhari@yahoo.com

**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**

**Phone**

+98 41 3332 1454

**Fax**

+98 41 3337 3950

**Email**

bilehjanii@tbzmed.ac.ir

**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*