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

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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
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Madani Heart Center, Daneshgah Street, Tabriz
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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
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Tabriz University of Medical Sciences, Daneshgah Street, Tabriz
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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
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
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Person responsible for updating data

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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