

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The Effect of vitamin C on inflammatory markers and hemodynamic parameters in patients undergoing Coronary Artery Bypass Surgery

#### Protocol summary

##### Summary

The aim of this study was to determine the effect of vitamin C on inflammatory markers and hemodynamic parameters in patients undergoing coronary artery bypass surgery on the heart center of Bushehr. So that if the drug reduces inflammatory markers, and have beneficial effects on hemodynamic parameters It can be as a safe and low-cost drugs to reduce the side effects of the inflammatory response induced by cardiopulmonary bypass can be used. Inclusion criteria: patients undergoing elective surgery and Exclusion criteria: drug reaction and any problems during surgery. This study is a randomized, controlled clinical trial with 80 male and female patients 18 years and older undergoing CABG surgery with cardiopulmonary bypass. The samples were block randomly assigned to either an experimental group and control blocks (40 patients in each group) are divided. For intervention to patients in the experimental group received 2 grams of vitamin C (4 ampoules 5CC) intravenously 10 minutes after induction of anesthesia and the patients in the control group normal saline solution of 4 ampoules 5 CC at the same time for intravenous injection will be. Blood samples were collected before the intervention and the end of 10 minutes and 24 hours after cardiopulmonary bypass surgery artery catheter to determine the amount of IL-6 and hsCRP and in the laboratory using enzyme-linked immunodeficient will be measured. The hemodynamic parameters measured at the same time the blood sample and will be registered in the check- list.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015120922466N10**

Registration date: **2016-06-13, 1395/03/24**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-06-13, 1395/03/24

##### Registrant information

###### Name

Shahnaz Pouladi

###### Name of organization / entity

Bushehr University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 917 374 0061

###### Email address

sh.pooladi@bpums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Bushehr University of Medical Sciences

##### Expected recruitment start date

2016-06-21, 1395/04/01

##### Expected recruitment end date

2016-08-22, 1395/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of vitamin C on inflammatory markers and hemodynamic parameters in patients undergoing Coronary Artery Bypass Surgery

##### Public title

The effect of vitamin C on inflammatory markers and hemodynamic parameters in patients undergoing coronary artery bypass surgery

## Purpose

Health service research

## Inclusion/Exclusion criteria

Inclusion criteria included patients undergoing elective coronary artery bypass graft surgery with cardiopulmonary bypass, aged between 40 and 80 years, at the same time non-malignant disease, no history of hypersensitivity reactions, patients with atrial fibrillation admitted lack of experience, lack of large trauma or major surgery less than 6 months of surgery, lack of ejection fraction less than 30%, not having kidney failure. Exclusion criteria: drug reaction and any problems with anesthesia during surgery, atrial fibrillation during operation.

## Age

From **40 years** old to **80 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## 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

Ethics committee of Bushehr University of Medical Sciences

##### Street address

Bushehr, sabz abad, Salman Farsi Avenue, Bushehr university of Medical Science, pardis site.

##### City

Busheher

##### Postal code

#### Approval date

2016-05-16, 1395/02/27

#### Ethics committee reference number

IR.BPUMS.REC.1395.31

## Health conditions studied

### 1

#### Description of health condition studied

Coronary Artery Bypass Surgery

#### ICD-10 code

T82.9

#### ICD-10 code description

T82.9 Unspecified complication of cardiac and vascular prosthetic device, implant and graft

## Primary outcomes

### 1

#### Description

Inflammatory markers (interleukin 6 and hsCRP)

#### Timepoint

10 minutes before the intervention and after the intervention (the end of CPB and 24 hours after surgery).

#### Method of measurement

Using the method of testing and enzyme-linked immunosorbent

### 2

#### Description

Hemodynamic parameters

#### Timepoint

10 minutes before the intervention and after the intervention (the end of CPB and 24 hours after surgery).

#### Method of measurement

check- list

## Secondary outcomes

### 1

#### Description

Gastrointestinal side effects

#### Timepoint

A week after intervention and at the end of intervention

#### Method of measurement

Visual

## Intervention groups

### 1

#### Description

Intervention group: 2 grams of Vitamin C (4 ampoules 5 ml) intravenously 10 minutes after induction of anesthesia

#### Category

Treatment - Drugs

### 2

#### Description

Control group: normal saline solution Equivalent 4 ampoules 5 ml intravenously 10 minutes after induction of anesthesia

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Heart Center of Bushehr

**Full name of responsible person**

Parisa Eskandari, Graduate Student in Nursing

**Street address**

Bushehr, Moalem street

**City**

Bushehr

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

University of Medical Sciences Bushehr, Vice  
chancellor for research

**Full name of responsible person**

Dr. Afshin Ostovar

**Street address**

Bushehr, Sabz abad, Salman Farsi Avenue, Bushehr  
university of Medical Science, Pardis Site.

**City**

Bushehr

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

University of Medical Sciences Bushehr, Vice chancellor  
for research

**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**

Bushehr University of Medical Sciences

**Full name of responsible person**

Shahnaz Pouladi

**Position**

Assistant professor

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

Bushehr, Sabz abad, Salman Farsi Avenue, Bushehr  
university of Medical Sciences, Pardis Site.

**City**

Bushehr

**Postal code**

7518759577

**Phone**

+98 77 3345 0187

**Fax**

+98 77 3345 2228

**Email**

Research(AT) Bpums.Ac.Ir; Sh.pooladi@bpums.ac.ir

**Web page address**

www.bpums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Bushehr University of Medical Sciences

**Full name of responsible person**

Shahnaz Pouladi

**Position**

Assistant Professor

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

Bushehr, sabz abad, Salman Farsi Avenue, Bushehr  
university of Medical Sciences, pardis site.

**City**

Bushehr

**Postal code**

7518759577

**Phone**

+98 77 3345 0187

**Fax**

+98 77 3345 2228

**Email**

Research(AT) Bpums.Ac.Ir; Sh.pooladi@bpums.ac.ir

**Web page address**

www.bpums.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Bushehr University of Medical Sciences

**Full name of responsible person**

Shahnaz Pouladi

**Position**

Assistant Professor

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

Bushehr, Sabz Abad, Salman Farsi Avenue, Bushehr  
University of Medical Sciences, Pardis Site.

**City**

Bushehr

**Postal code**

7518759577

**Phone**

+98 77 3345 0187

**Fax**

+98 77 3345 2228

**Email**

Research(AT) Bpums.Ac.Ir; Sh.pooladi@bpums.ac.ir

**Web page address**

www.bpums.ac.ir

**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*