

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Effect of postoperative active warming of patient on bleeding and coagulation factor function after off-pump coronary artery bypass graft surgery

#### Protocol summary

##### Summary

The main objective of this study is to determine the effect of postoperative active warming of patient on bleeding and coagulation factor after off-pump coronary artery bypass graft surgery. This randomized clinical trial will be performed on 60 patients undergoing off-pump coronary artery bypass graft surgery. Inclusion criteria consist of: Patients are candidate for OPCAB, between 30-70 years old, no history of previous CABG, Normal coagulation tests include: pt, ptt and platelet count before surgery, ventricular ejection fraction more than 35% of output, The absence of preoperative coagulation disorders, written informed consent to participate in the study. exclusion criteria consist of: need for high dose inotrope after CABG, Need for IABP in perioperation, Need for cardiopulmonary bypass intra operation. in intervention group: Active warming of patient will be started after admission in ICU (to reach 36.7°C). in control group will be used a bedsheet. Chest tube drainage will be recorded 6 and 24 hours after the operation. Packed red blood cell requirement will be recorded 24 hours after the operation. coagulation profiles will be recorded immediately after and 6 hours after the operation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013111315395N1**

Registration date: **2014-06-14, 1393/03/24**

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

Last update:

Update count: **0**

##### Registration date

2014-06-14, 1393/03/24

#### Registrant information

##### Name

razie zare bezg abadi

##### Name of organization / entity

shahid sadoughi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 52 35971

##### Email address

zare.razie@ssu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Yazd shahid sadoughi university of Medical Sciences

#### Expected recruitment start date

2014-01-21, 1392/11/01

#### Expected recruitment end date

2014-06-22, 1393/04/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of postoperative active warming of patient on bleeding and coagulation factor function after off-pump coronary artery bypass graft surgery

#### Public title

Effect of warming of patient on bleeding and coagulation factor after coronary artery bypass graft surgery

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: Patients are candidate for OPCAB

between 30-70 years old; no history of previous CABG; Normal prothrombin time partial thromboplastin time and platelet count before surgery; ventricular ejection fraction more than 35% of output; written informed consent to participate in the study. exclusion criteria: need for high dose inotrope after CABG; Need for IABP in perioperation; Need for cardiopulmonary bypass intraoperation.

#### **Age**

From **30 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)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Yazd University of Medical Sciences

###### **Street address**

Bahonar Square, Headquarters Yazd University

###### **City**

Yazd

###### **Postal code**

8916877443

##### **Approval date**

2013-10-21, 1392/07/29

##### **Ethics committee reference number**

17/1/141446/پ

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Coronary artery Bypass Graft Patients

##### **ICD-10 code**

I25.1

##### **ICD-10 code description**

Atherosclerotic heart disease

### **Primary outcomes**

#### **1**

##### **Description**

Level of prothrombin time, activated partial thromboplastin time, and platelet count

##### **Timepoint**

At time zero and 6 hours after surgery

##### **Method of measurement**

prothrombin time and activated partial thromboplastin time measured by second and platelet count by number in cubic millimeter

#### **2**

##### **Description**

The rate of postoperative bleeding

##### **Timepoint**

At 6 and 24 hours after surgery

##### **Method of measurement**

Measure Chest bottle drainage by cc

### **Secondary outcomes**

#### **1**

##### **Description**

Packed red blood cells transfused

##### **Timepoint**

24 hours after surgery

##### **Method of measurement**

number of units of packed red blood cells transfused within 24 hours after operation

### **Intervention groups**

#### **1**

##### **Description**

in control group will be used a bedsheet

##### **Category**

Prevention

#### **2**

##### **Description**

in intervention group: Active warming of patient will be started after admission in ICU (to reach 36.7°C).

##### **Category**

Prevention

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Yazd Afshar Hospital

**Full name of responsible person**

Mrs. H.Deighani

**Street address**

Yazd University of Medical Sciences, School of Nursing

**City**

Yazd

**Fax****Email**

zare.razie1@gmail.com zare.razie@ssu.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Sadoughi University of Medical Sciences, Iran

**Full name of responsible person**

Mrs. H.Deighani

**Position**

Bachelor of Nursing

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

School of Nursing, St Bou Ali, Brigadier Fallahi Boulevard, yazd, iran

**City**

Yazd

**Postal code**

8916877443

**Phone**

+98 35 1824 1754

**Fax****Email**

hamide.deighani@yahoo.com

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Dr.f.Ezoddini

**Street address**

Vice chancellor for research, Shahid Sadoughi University of Medical Sciences

**City**

Yazd

**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, Shahid Sadoughi 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**

Shahid Sadoughi University of Medical Sciences, Yazd, School of Nursing

**Full name of responsible person**

Razie Zare Bezg abadi

**Position**

Student nurse in master of critical care nursing

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

Afshar hospital, Jomhuory Boulevard, Yazd, Iran

**City**

Yazd

**Postal code**

8916877443

**Phone**

+98 35 1523 5971

**Person responsible for updating data****Contact****Name of organization / entity**

Yazd University of Medical Sciences, School of Nursing

**Full name of responsible person**

Razie Zare Bezg abadi

**Position**

Master Nurse Student of critical care nursing

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

Afshar hospital, Jomhuory Boulvar, Yazd, Iran

**City**

Yazd

**Postal code**

8916877443

**Phone**

+98 35 1523 5971

**Fax****Email**

zare.razie1@gmail.com zare.razie@ssu.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*