

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of preaortic fat pad preservation on atrial fibrillation post off-pump coronary artery bypass grafting (CABG)

#### Protocol summary

##### Summary

Objective: The purpose of this study is to evaluate the effect of periaortic fat pad removal during coronary artery bypass grafting on the autonomic nervous system tone, incidence of postoperative atrial fibrillation, length of hospital stay, in-hospital morbidity and mortality. Inclusion and exclusion criteria: Patients who scheduled to undergo their first coronary artery bypass grafting aged 35-75 will be included. Patients will be excluded if; a) have repeated CABG, b) have concomitant valve replacement procedure, c) have thyroid dysfunction, d) 4. drink alcohol, e) have CRF, f) have history of atrial fibrillation, g) have history of mitral regurgitation or mitral stenosis and h) refused to participate. Study participants: Patients who scheduled to undergo their first coronary artery bypass grafting in Afshar Heart Centre of Yazd aged 35-75 years. Sample size: 180 Intervention and time: Periaortic fat pad removal during coronary artery bypass grafting. Primary outcome: Postoperative atrial fibrillation, length of hospital stay, in-hospital morbidity and mortality.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013042013071N1**

Registration date: **2014-11-26, 1393/09/05**

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

Last update:

Update count: **0**

##### Registration date

2014-11-26, 1393/09/05

##### Registrant information

###### Name

Neda Fotoohi Ardakani

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 1820 8164

##### Email address

masoud.mirzaei@sydney.edu.au

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Sadoughi University of Medicine Sciences

##### Expected recruitment start date

2014-09-20, 1393/06/29

##### Expected recruitment end date

2014-12-20, 1393/09/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of preaortic fat pad preservation on atrial fibrillation post off-pump coronary artery bypass grafting (CABG)

##### Public title

Effect of preaortic fat pad preservation on arrhythmia

##### Purpose

Diagnostic

##### Inclusion/Exclusion criteria

Inclusion criteria: Candidate for CABG and being in the 35-75 years age group. Patients were excluded if; had repeat CABG, concomitant valve replacement procedure, thyroid dysfunction, alcoholism, CRF, History of AF, History of mitral regurgitation or mitral stenosis and refused to participate.

##### Age

From **35 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **180**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

### 1

**Registry name**

masoud.mirzaei@sydney.edu.au

**Secondary trial Id**

3zx3

**Registration date**

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Shahid Sadoughy University of Medical Sciences

**Street address**

Bahonar sqr.Yazd

**City**

Yazd

**Postal code**

89491-61211

**Approval date**

2012-03-03, 1390/12/13

**Ethics committee reference number**

130344

## Health conditions studied

### 1

**Description of health condition studied**

Post coronary artery bypass grafting atrial fibrillation

**ICD-10 code**

I48

**ICD-10 code description**

Atrial fibrillation and flutter

### 2

**Description of health condition studied**

impact of AFP maintenance on the hospital length of stay

**ICD-10 code**

T82.2

**ICD-10 code description**

Mechanical complication of coronary artery bypass and valve grafts

## Primary outcomes

### 1

**Description**

post CABG atrial fibrillation

**Timepoint**

Immediately after bypass surgery until discharge from the hospital

**Method of measurement**

in Intensive care unit with evaluation of continuous monitoring print and for Hospitalized patients with electrocardiography every 6 hours or when the patient is symptomatic

### 2

**Description**

to evaluate hospital length of stay, and determine the impact of AFP retention on several safety parameters (another arrhythmia, myocardial infarction, bradycardia, mortality, and stroke)

**Timepoint**

24 hours after intervention

**Method of measurement**

Time, ECG, troponin test

## Secondary outcomes

### 1

**Description**

Other cardiac arrhythmias, mortality and morbidity rates, length of hospital stay

**Timepoint**

Immediately after the intervention until discharge from hospital

**Method of measurement**

Continuous monitoring in the intensive care unit, ECG every 6 hours daily patient visits and questionnaires

## Intervention groups

### 1

**Description**

Retain fat pad around the aorta during coronary artery bypass surgery in the intervention group

**Category**

Treatment - Surgery

## 2

### Description

Standard coronary artery bypass grafting in the control group

### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Afshar Heart Centre

##### Full name of responsible person

Mahdi Hadadzadeh

##### Street address

##### City

Yazd

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Sadughi University of Medical Sciences

##### Full name of responsible person

Masoud Mirzaei

##### Street address

Afshar Heart Hospital

##### City

Yazd

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shahid Sadughi 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

Afshar Heart Centre

##### Full name of responsible person

Neda Fotoohi Ardakani

##### Position

GP

#### Other areas of specialty/work

#### Street address

Afshar Heart Centre, Jomhoori Blvd, Yazd

#### City

Yazd

#### Postal code

#### Phone

+98 35 1820 8164

#### Fax

#### Email

neda.fotoohi@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Sadughi University of Medical Sciences

##### Full name of responsible person

Mahdy Hadadzadeh

##### Position

Cardiovascular Surgeon

##### Other areas of specialty/work

##### Street address

Afshar Heart Centre, Jomhoory Blvd, Yazd

##### City

Yazd

##### Postal code

##### Phone

+91 23960355

##### Fax

##### Email

mehad51@yahoo.com

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Afshar Heart Centre of Yazd

##### Full name of responsible person

Masoud Mohammadi

##### Position

MSc of Epidemiology

##### Other areas of specialty/work

##### Street address

Jomhoori Blvd.

##### City

Yazd

##### Postal code

##### Phone

+98 35 1524 1214

##### Fax

##### Email

mmirzaei@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*