

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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Iran (Islamic Republic of)

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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

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Other areas of specialty/work

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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