

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Effect of goal directed fluid therapy on outcomes of patients admitted to ICU following off-pump CABG

Protocol summary

Summary

70 adult patients admitted to ICU after off-pump CABG are recruited for the study. they will randomly divided to either TED (n=35) or control (n=35) groups based on a computed based randomization system. . the patients will be matched regarding risk of the surgery according to EURO II Score. patients in the TED group will receive intravenous fluid based on hemodynamic parameters including (flow time corrected) FTc, SVI (sstroke volume index), and CI (cardiac index). Fluid therapy will be according to 4-2-1 rule and using heart rate, blood pressure, CVP, and urine output. VBG is taken during 24 hours for lactate and SCVO2 measurements. the primary outcome is comparison of in hospital mortality between the two groups. The secondary outcome include comparing length of hospital stay, nausea, vomiting, renal failure, blood transfusion requirement, mechanical ventilation time, inotrope and vasopressor administration, base deficient, lactate level, and ScVO2.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015103021098N2**

Registration date: **2017-07-05, 1396/04/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-05, 1396/04/14

Registrant information

Name

Shahram Amini

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Mashhad university of medical sciences

Expected recruitment start date

2015-11-06, 1394/08/15

Expected recruitment end date

2016-02-04, 1394/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of goal directed fluid therapy on outcomes of patients admitted to ICU following off-pump CABG

Public title

Effect of goal directed fluid therapy on outcomes of patients admitted to ICU following off-pump CABG

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria All adult patients undergoing off-pump CABG Exclusion criteria EF< 40 %; significant valvular disease; obvious coagulopathy; emergency surgery; renal failure, liver failure; heart failure; oropharyngeal pathology; gastric surgery; age > 70 years; patients with high derangement and hypotensive patients treated with inotrope and vasopressor

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

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

0000000

Secondary trial Id

000000

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Ghoreishi office, Daneshgah avenue

City

Mashhad

Postal code

Approval date

2015-10-28, 1394/08/06

Ethics committee reference number

ir.mums.fm.rec.1394.409

Health conditions studied

1

Description of health condition studied

Ischaemic heart diseases

ICD-10 code

I20-I25

ICD-10 code description

Acute myocardial infarction

Primary outcomes

1

Description

blood lactate, SCVO2

Timepoint

During hospital stay

Method of measurement

LACTATE (meq/l) scvo2 (%)

Secondary outcomes

1

Description

mortality

Timepoint

During hospital stay

Method of measurement

Numbers

Intervention groups

1

Description

intervention (group 1) fluid therapy by using esophageal Doppler

Category

Treatment - Other

2

Description

control (group 2) conventional fluid therapy

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital, OPEN HEART SURGERY ICU

Full name of responsible person

dr. Shahram Amini

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

shahram amini

Street address
Imam Reza hospital
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
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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