

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of patients' outcome in open cardiac surgery with two methods of blood glucose control:1-Tight 2-Conventional

Protocol summary

Summary

The purpose of the study: Compared the outcome of patients undergoing open cardiac surgery to two methods of glycemic control: 1- Tight Control2- Conventional. Inclusion criteria: Diabetes; Age:18-70; ASA 2-3; All of on pump cardiac surgery Exclusion criteria: Off pump cardiac surgery; Ketoacidosis or Hyperosmolar coma; Redosurgery; History of TIA or CVA. In this open label randomized clinical trial 74 diabetic patients undergoing open heart surgery will enrolled in the two groups. if the blood sugar is above 100 mg /dL) in group 1 insulin infusion rate is adjusted according to blood glucose between 100-120mg/dl. Patients in group 2 were BS greater than or equal to 200 mg/dl can be treated with insulin. Mortality, Sternal wound infection, Duration of mechanical ventilation, Cardiac arrhythmia, Cerebrovascular attack and Acute renal failure are primary outcomes. 30 days after discharge, patients were seen by the surgeon and the occurrence of adverse events are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013041713052N1**

Registration date: **2013-07-09, 1392/04/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-09, 1392/04/18

Registrant information

Name

Fatemeh Javaherforoosh Zadeh

Name of organization / entity

Jondishapoor University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Resources Research Council of Shiraz University of Medical Sciences

Expected recruitment start date

2013-03-19, 1391/12/29

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of patients' outcome in open cardiac surgery with two methods of blood glucose control:1- Tight 2-Conventional

Public title

Impact on outcome of glycemic control in diabetic patients undergoing open heart surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Diabetes; Age:18-70; ASA 2-3; All of on pump cardiac surgery Exclusion criteria: Off pump cardiac surgery; Ketoacidosis or Hyperosmolar coma; Redosurgery; History of TIA or CVA

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **74****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Council of Shiraz University of Medical Sciences

Street address

6/2, Golab Lane ,Hengam St Niayesh blv

City

Shiraz

Postal code**Approval date**

2013-07-24, 1392/05/02

Ethics committee reference number

91-01-60-5268

Health conditions studied**1****Description of health condition studied**

daiabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

dedth

Timepoint

in the ICU and after 30 days

Method of measurement

Observation of ECGflat

2**Description**

wound infection

Timepoint

in the ICU and after 30 days

Method of measurement

Observation

3**Description**

mechanical ventilation time

Timepoint

in the ICU

Method of measurement

hours after arival in the ICU

4**Description**

cardiac aritmia

Timepoint

in the ICU and after 30 days

Method of measurement

with ECG

5**Description**

stroock

Timepoint

in the ICU and after 30 days

Method of measurement

with symptoms

6**Description**

ARF

Timepoint

in the ICU and after 30 days

Method of measurement

WITH BUN,cr

Secondary outcomes**1****Description**

ICU staying

Timepoint

from arival to discharg from ICU

Method of measurement

DAY

Intervention groups

1

Description

In the intervention group, glycemic control using insulin to target blood glucose 100- 120 done

Category

Treatment - Drugs

2

Description

In the control group, the treatment of blood glucose greater than 200 target value 180-200mg/dl.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihy Hospital

Full name of responsible person

Dr Fatemeh Javaherforoosh Zadeh

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Shiraz University of Medical Sciences

Full name of responsible person

Dr G.R.Hatam

Street address

Shahid Faghihi Hospital

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Council of Shiraz 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

Jondishapoor University Of Medical Sciences

Full name of responsible person

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Position

Anesthesiologist

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