Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of patients' outcome in open cardiac surgery with two methods of blood glucose control:1-Thigt 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 pomp cardiac surgery Exclusion criteria: Off pomp cardiac surgery; Ketoasidosis 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

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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-Thigt 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 pomp cardiac surgery Exclusion criteria: Off pomp cardiac surgery; Ketoasidosis 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 size
Target 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
mecanical 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
strock
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 glucose100- 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
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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