

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of Hyperglycemia Treatment on Complications Rate after Pediatric Cardiac Surgery.

Protocol summary

Summary

Objective: Studying the effect of tight control of blood glucose on complications rate after Pediatric cardiac surgery. Design: Prospective randomized clinical trial
Setting and conduct: Fifty pediatric patients under 12 years olds candidate for elective cardiac surgery, randomly will be allocated in two Insulin and placebo groups (N=25). Inclusion criteria: Patients under 12 Years olds who are candidate for elective cardiac surgery With cardiopulmonary bypass. Exclusion criteria: Diabetics; Urgent surgery; Multi-organ failure; Left ventricle Ejection fraction lower than 40 %; Redo surgery. Intervention: Starting infusion of Insulin regular 0.1 u/ ml after induction of anesthesia up to end of Surgery in study group, and infusion of saline normal in placebo group. Outcome measures: Postoperative mortality and morbidity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052316117N2**
Registration date: **2014-10-15, 1393/07/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-15, 1393/07/23

Registrant information

Name

Bahman Naghipour Basmenj

Name of organization / entity

Tabriz Univesity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

naghipourb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-10-22, 1393/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Hyperglycemia Treatment on Complications Rate after Pediatric Cardiac Surgery.

Public title

Effect of Hyperglycemia Treatment on Complications Rate after Pediatric Cardiac Surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : Childeren with age under 12 years undergoing cardiac surgery with cardiopulmonary bypass (CPB). Exclusion criteria : Diabetics; Urgent surgery; Multi-organ failure; Left ventricle Ejection fraction lower than 40 %; Redo surgery.

Age

From **1 day** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization with online software (random.org)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Golgasht, Daneshgah Street, Tabriz

City

Tabriz

Postal code

Approval date

2013-11-18, 1392/08/27

Ethics committee reference number

92139

Health conditions studied

1

Description of health condition studied

Complications of pediatric heart surgery

ICD-10 code

Y83.9

ICD-10 code description

Surgical procedure, unspecified

Primary outcomes

1

Description

Postoperative complications

Timepoint

Hospital stay and ICU stay time period

Method of measurement

Questionnaire

2

Description

Mortality rate

Timepoint

Hospital stay and ICU stay time period

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group : Starting infusion of Insulin regular 0.1 u/ ml after induction of anesthesia up to end of Surgery.

Category

Treatment - Drugs

2

Description

Control group : Infusion of saline normal during surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Madani Hospital

Full name of responsible person

Dr. Bahman Naghipour

Street address

Madani Heart Center, Daneshgah Street, Tabriz.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Reza Rashidi

Street address

Tabriz University of Medical Sciences, Daneshgah Street, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for Research of Tabriz 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
empty

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Medicine faculty, Tabriz University of Medical Sciences

Full name of responsible person
Hassan SoleimanPour

Position
Vice Chancellor for research of Medicine faculty

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position
Assistant Professor in Anesthesiology

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Assistant Professor in Anesthesiology

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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