

# 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

+98 41 3337 3950

##### 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

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences

**Full name of responsible person**  
Dr. Bahman Naghipour

**Position**  
Assistant Professor in Anesthesiology

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Tabriz University of Medical Sciences

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Dr. Bahman Naghipour

**Position**  
Assistant Professor in Anesthesiology

**Other areas of specialty/work**

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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*