

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of infusion of GIK(Glucose-Insulin-Potassium) solution on clinical outcomes after heart surgery under cardiopulmonary bypass in children in Shahid Chamran Hospital in 2016

Protocol summary

Study aim

Determining the effect of administration of glucose, insulin, potassium (GIK) on clinical outcomes after pediatric cardiopulmonary bypass surgery in comparison with the control group

Design

This is a one-stop clinical trial with parallel groups that randomly assign individuals to each group.

Settings and conduct

This study was conducted at Shahid Chamran Hospital in Isfahan. Blinding in this study was one-sided blind, in which the only anesthesiologist was aware of the type of treatment being prescribed.

Participants/Inclusion and exclusion criteria

Pediatric Heart Disease Candidate for Heart Surgery under the Pulmonary Pump Age less than 12 years Parental consent to participate in the study And exit criteria Disagreement with parents

Intervention groups

In the first group, the intervention group, glucose-insulin-potassium (GIK) solution was infused in ICU after induction of anesthesia up to 12 hours after surgery. The second group, the control group, was equivalent to the amount of solution received in the normal saline infusion group.

Main outcome variables

Arrhythmia; need for shock and injection of inotrop; duration of mechanical ventilation; duration of hospitalization in the ICU and section; incidence of renal failure and the need for dialysis; duration of sternum openness

General information

Reason for update

Acronym

GIK solution

IRCT registration information

IRCT registration number: **IRCT20190109042306N1**

Registration date: **2019-02-16, 1397/11/27**

Registration timing: **retrospective**

Last update: **2019-02-16, 1397/11/27**

Update count: **0**

Registration date

2019-02-16, 1397/11/27

Registrant information

Name

Azade tavangar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7735 7593

Email address

abbaskhodaeimehr@hlth.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

2015-03-21, 1394/01/01

Actual recruitment end date

2016-03-19, 1394/12/29

Trial completion date

2016-03-19, 1394/12/29

Scientific title

Effect of infusion of GIK(Glucose-Insulin-Potassium) solution on clinical outcomes after heart surgery under

cardiopulmonary bypass in children in Shahid Chamran Hospital in 2016

Public title

Effect of administration of GIK (Glucose-Insulin-Potassium) Solution on clinical outcomes after heart surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pediatric Heart Disease Candidate for Heart Surgery under the Pulmonary Pump Age less than 12 years Parental consent to participate in the study

Exclusion criteria:

Disagreement with parents

Age

To **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

All eligible patients were randomly assigned to the intervention group and the control group based on the last digit of the hospital identification number. randomization was performed as one-side-blind in such a way that only an anesthetist was aware of the type of intervention given to each patient.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, with the exception of the anesthetist, all patients were unaware of the type of treatment received

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib Ave, Darvaze Shiraz

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2014-04-25, 1393/02/05

Ethics committee reference number

395674

Health conditions studied

1

Description of health condition studied

Children with heart disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Clinical outcomes after pediatric cardiac surgery under a cardiac pulmonary pump

Timepoint

Measurements were performed before the cardiovascular pump was connected to the end of the surgery every hour and at the ICU every 6 hours

Method of measurement

Blood glucose and blood pressure tests were performed using the appropriate test

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group (GIK group): In this group, glucose-insulin-potassium (GIK) solution was infused in ICU after induction of anesthesia up to 12 hours after surgery. The dosages were: insulin 0.05 units per kg / h, glucose 0.5 g / kg / h, and potassium 0.5 mg / kg / h.

Category

Treatment - Drugs

2

Description

Control group: In this group, normal saline solution was injected in the same volume as the intervention group (20 cc)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Chamran Hospital in Isfahan
Full name of responsible person
Azade Tavangar
Street address
Hezar Jarib Ave, Darvaze Shemiran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
shaghayegh hagh jooy javanmard
Street address
Hezar Jarib Ave, Darvaze Shiraz
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
50
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Azade Tavangar
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available