

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparative evaluation of blood glucose changes, during surgery in children 6 months to 4 years old under 1/5-4/5, ringer and 1/3-2/3 injectable fluid

Protocol summary

Study aim

Determining the effect of three types of fluid therapy with one-fifth to four-fifths, Ringer and one-third to two-thirds on blood glucose levels in children aged 0.5-4 years undergoing surgery

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, Phase 3 on 105 children.

Settings and conduct

In this study, 105 children undergoing surgery were randomly assigned in three groups of 35 and intraoperative fluid therapy was performed in the three groups with serum one-fifth-four-fifth, Ringer and one-third-two-thirds, respectively, and blood glucose levels, hemodynamic and electrolyte parameters of patients were measured and compared before surgery to 24 hours after surgery.

Participants/Inclusion and exclusion criteria

Entry requirements: Age range 6 months to 4 years, candidate for surgery under general anesthesia, Exit conditions: Diabetes Mellitus type 1

Intervention groups

Intervention group 1: one-fifth four-fifths. Intervention group 2: one third two thirds. Control group: Ringer.

Main outcome variables

Blood pressure, Blood oxygen saturation percentage, Respiration rate, Body temperature, Blood sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200515047453N1**

Registration date: **2021-02-20, 1399/12/02**

Registration timing: **retrospective**

Last update: **2021-02-20, 1399/12/02**

Update count: **0**

Registration date

2021-02-20, 1399/12/02

Registrant information

Name

Maryam Ashrafi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 5550 0111

Email address

m.ashrifi7122@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-02, 1398/02/12

Expected recruitment end date

2019-09-10, 1398/06/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of blood glucose changes, during surgery in children 6 months to 4 years old under 1/5-4/5, ringer and 1/3-2/3 injectable fluid

Public title

Comparative evaluation of blood glucose changes, during surgery in children 6 months to 4 years old

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age range 6 months to 4 years Consent of the patient's parents to participate in the study ASA=1,2 Candidate for surgery under general anesthesia

Exclusion criteria:
Patient with type 1 diabetes

Age
From **6 months** old to **4 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
They are randomly distributed in three groups of 35 people using the card folding method. In this method, a number of cards or letters selected by the researcher as the first group and the same number of cards for the next second and third groups are considered; Then, by merging the cards together (flipping the cards), a card is taken out and its allocation is recorded. The cards are then merged again and another card is removed. This process continues until a random sequence is reached according to the sample size (35).

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not 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

Isfahan University of Medical science-Hezar Jarib Avenue, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8739118631

Approval date

2017-05-30, 1396/03/09

Ethics committee reference number

IR.MUI.REC.1396.3.953

Health conditions studied

1

Description of health condition studied

blood glucose

ICD-10 code

R73.09

ICD-10 code description

Other abnormal glucose

Primary outcomes

1

Description

Blood sugar level

Timepoint

Hemodynamic parameters are measured and recorded every 15 minutes during surgery and recovery and blood sugar levels at baseline and every one hour during surgery and 2 hours after surgery.

Method of measurement

Glucometer, ABG

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One-fifth four-fifths, Dextrose serum 10% Ghazi 0.5 liters made in Iran and Shahid Ghazi Pharmaceutical Company, hemodynamic parameters every 15 minutes during operation and recovery and blood sugar level at baseline with blood sample, every hour during operation and end of operation with glucometer and 2 hours After surgery with blood sample, electrolyte is measured before and 2 hours after surgery, blood acidity is measured and recorded at 2 hours postoperatively through ABG and urinary output at the end of surgery and at the end of recovery and 2 hours after surgery.

Category

Diagnosis

2

Description

Intervention group: One third two thirds, Dextrose serum 10% Ghazi 0.5 liters made in Iran and Shahid Ghazi Pharmaceutical Company, hemodynamic parameters every 15 minutes during operation and recovery and blood sugar level at baseline with blood sample, every hour during operation and end of operation with

glucometer and 2 hours After surgery with blood sample, electrolyte is measured before and 2 hours after surgery, blood acidity is measured and recorded at 2 hours postoperatively through ABG and urinary output at the end of surgery and at the end of recovery and 2 hours after surgery.

Category

Diagnosis

3

Description

Intervention group: Ringer, Ringer Lactate Serum 10% Ghazi 0.5 liters Made in Iran and Shahid Ghazi Pharmaceutical Company, Hemodynamic parameters every 15 minutes during surgery and recovery and blood sugar level at baseline with blood sample, every hour during surgery and end of operation with glucometer and 2 Postoperative saturation with blood sample, electrolyte before and 2 hours after surgery, blood acidity at 2 hours postoperatively through ABG and urinary output at the end of surgery and at the end of recovery and 2 hours after surgery are recorded.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra and Imam Hossein hospital in Isfahan

Full name of responsible person

Maryam Ashrafi

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Hezar Jarib Ave,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

100

Public or private sector

Public

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

Parvin Sajedi

Position

Associated

Latest degree

Ph.D.

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Parvin Sajedi

Position

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Latest degree

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Other areas of specialty/work

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Fax**Email**

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Some of the information can be shared

When the data will become available and for how long

4 months after printing the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

No analysis will be allowed

From where data/document is obtainable

Email address

What processes are involved for a request to access data/document

Request by e-mail

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Ashrafi

Position

Medicine

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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