

# 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)

###### Phone

+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

**Street address**

Hezar Jarib Ave,

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8739118631

**Phone**

+98 31 5550 0111

**Email**

m.ashrufi7122@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Maryam Ashrafi

**Street address**

Hezarjarib Ave,

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8739118631

**Phone**

+98 31 5550 0111

**Email**

m.ashrufi7122@yahoo.com

**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

**Street address**

Hezarjarib Ave,

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8739118631

**Phone**

+98 31 5550 0111

**Email**

sajedi@med.mui.ac.ir

**Person responsible for scientific 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

**Street address**

Hezarjarib Ave,

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8739118631

**Phone**

+98 31 5550 0111

**Email**

sajedi@med.mui.ac.ir

**Phone**

+98 31 5550 0111

**Fax****Email**

m.ashrufi7122@yahoo.com

**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

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib St,  
Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8739118631