

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparison of administration of oral dextrose with intravenous infusion of 1/3 2/3 serum, on the incidence of hypoglycemia in children 2-6 years old candidate for minor surgery under general anesthesia

Protocol summary

Study aim

Investigation of blood sugar changes during minor surgery in two to six-year-old children in two groups of oral administration of sugar or continuous intravenous injection of serum 1/3 2/3.

Design

Randomized clinical trial with randomized double-blind randomized groups on 66 patients with SPSS software

Settings and conduct

Group I included children who had npo after midnight for surgery the next morning, and during the npo period, serum 1/3 2/3 was infused according to the formula for calculating the amount of maintenance fluid until the operation. Group II included those who received 10 ml per kg body weight of 5% glucose two hours before the start of surgery. The first glucose was checked after induction of anesthesia and the second glucose was checked 30 minutes after induction of anesthesia. Hypoglycemia was defined as hypoglycemia less than 50mg/kg and hyperglycemia was defined as hypoglycemia above 150mg/dl.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 2-6 years old, candidate for minor surgery under general anesthesia. Exclusion criteria: Diabetic patients, Patients with a history of hypoglycemia, Metabolic diseases, and History of seizures.

Intervention groups

Group one: Patients receiving serum 1/3 2/3. Group Two: Patients receiving oral sugar.

Main outcome variables

Measurement of blood sugar every half hour after surgery begins to the end of the operation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220523054970N1**

Registration date: **2023-03-29, 1402/01/09**

Registration timing: **retrospective**

Last update: **2023-03-29, 1402/01/09**

Update count: **0**

Registration date

2023-03-29, 1402/01/09

Registrant information

Name

Kaveh Latifinaibin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4427 5434

Email address

dr.latifikaveh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2020-09-22, 1399/07/01

Trial completion date

2020-09-22, 1399/07/01

Scientific title

Comparison of administration of oral dextrose with

intravenous infusion of 1/3 2/3 serum, on the incidence of hypoglycemia in children 2-6 years old candidate for minor surgery under general anesthesia

Public title

Comparison of administration of oral dextrose with intravenous infusion of 1/3 2/3 serum, on the incidence of hypoglycemia

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Children 2-6 years old, candidate for minor surgery under general anesthesia

Exclusion criteria:

Diabetic patients Patients with a history of hypoglycemia Metabolic diseases History of seizures

Age

From **2 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **66**

Actual sample size reached: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

In this intervention study, which was conducted as a randomized clinical trial, the study subjects were selected based on a simple random table. To use the table of random numbers, we first defined the framework of our statistical society; That is, the exact number of people in the society was known and they were assigned a code respectively. To select sample people from the table, it was randomly started from a point of the table in the direction of row or column. The selected number was actually the code of an individual from the community that is selected as a sample.

Blinding (investigator's opinion)

Double blinded

Blinding description

The anesthetic technicians of the patients who checked their blood sugar and then the note were unaware of the type of intervention. Patients also did not understand the type of clinical intervention due to their young age.

Placebo

Not used

Assignment

Parallel

Other design features

No study has been conducted in this field in Iran.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Tehran Hemat Highway next to Milad Tower. 14535

City

Tehran

Province

Tehran

Postal code

14535

Approval date

2019-11-19, 1398/08/28

Ethics committee reference number

IR.IUMS.FMD.REC.1398.355

Health conditions studied

1

Description of health condition studied

Hypoglycemia

ICD-10 code

E16.2

ICD-10 code description

Hypoglycaemia, unspecified

Primary outcomes

1

Description

Reducing the incidence of hypoglycemia and its complications

Timepoint

The blood glucose was checked first after the induction and the second blood glucose was checked after 30 minutes of induction

Method of measurement

Blood glucose was measured using a glucometer sensor.

2

Description

Hypoglycemia was defined as blood glucose less than 50 mg / kg and hyperglycemia was defined as blood glucose above 150 mg / dl.

Timepoint

The blood glucose was checked first after the induction and the second blood glucose was checked after 30 minutes of induction

Method of measurement

Blood glucose was measured using a glucometer sensor.

Secondary outcomes

1

Description

Hemodynamics including heart rate, systolic blood pressure and mean arterial pressure (MAP)

Timepoint

before induction of anesthesia and every 5 minutes to 20 minutes thereafter

Method of measurement

Based on blood pressure cuff

Intervention groups

1

Description

The first intervention group: included patients who were fasting after midnight for surgery the next morning, and during the fasting period, maintenance 1/3 2/3 serum was calculated at 5 ml/kg per hour and was infused until the time of surgery.

Category

Other

2

Description

Intervention group: The second intervention group: this group included patients who received oral 5% glucose 10 ml/kg two hours before surgery.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar Hospital

Full name of responsible person

Mansour Gholami

Street address

5th floor, No. 116, 12th St., Shahriar St, Salmas Square, Yusef Abad

City

Tehran

Province

Tehran

Postal code

1431735676

Phone

+98 916 305 3296

Email

Mansourgh@rocketmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein keivani

Street address

Tehran Hemat Highway next to Milad Tower. 14535

City

Tehran

Province

Tehran

Postal code

14535

Phone

+98 21 8670 1021

Email

Mansourgh@rocketmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mansour Gholami

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

یوسف آباد-میدان سلماس-خیابان شهریار-خیابان 12-پلاک 116-طبقه 5

City

Tehran

Province

Tehran

Postal code

1431735676

Phone

+98 916 305 3296

Email

Mansourgh@rocketmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mansour Gholami

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Yousef Abad, Salmas Sq., Shahriar St., 12th St., No. 116, 5th floor

City

Tehran

Province

Tehran

Postal code

1431735676

Phone

+98 21 8863 0346

Email

Mansourgh@rocketmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mansour Gholami

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Yousef Abad, Salmas Sq., Shahriar St., 12th St., No. 116, 5th floor

City

Tehran

Province

Tehran

Postal code

1431735676

Phone

+98 21 8863 0346

Email

Mansourgh@rocketmail.com

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

Due to the confidentiality of patients

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available