Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of effect of preoperative oral carbohydrate on the blood glucose and hemodynamics in children under 3 years old undergoing elective inguinal surgeries

Protocol summary

Study aim
Evaluation of effect of preoperative oral carbohydrate on the blood glucose and hemodynamics in children under 3 years old undergoing elective inguinal surgeries

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 207 patients

Settings and conduct
In this study, a double-blind clinical trial was performed on 207 children under the age of three in three groups (first group: oral carbohydrates, second group: drinking water, third group: standards guidelines for fasting before surgery) equal to 69 patients in each group who were candidates for elective surgery. In Urmia Children's hospital, before induction of anesthesia and during surgery and recovery, patients' blood sugar will be measured by a glucometer. Mean arterial pressure and heart rate will be measured every 5 minutes for 20 minutes. Vomiting will be recorded at the time of induction of anesthesia and after withdrawal from anesthesia until discharge from recovery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Elective surgeries, American Society of Anesthesiologists (ASA) I and II, Age less than 3 years; Exclusion criteria: Emergency surgeries, Having heart, lung and liver diseases, Having metabolic diseases, Having diabetes, Glucose 6-phosphate deficiency

Intervention groups
In the intervention group, 5 ml / kg of 20% dextrose solution made by Samen Pharmaceutical Company will be prepared orally for surgery in the pediatric surgery ward 2 hours before surgery, and in the control group, 5 ml / kg drinking water will be prescribed two hours before surgery. One group will fast according to pre-surgery standards.

Main outcome variables
Blood sugar, vomiting, mean arterial pressure, heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170516033992N7**
Registration date: **2021-08-29, 1400/06/07**
Registration timing: **prospective**

Last update: **2021-08-29, 1400/06/07**
Update count: **0**

Registration date
2021-08-29, 1400/06/07

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3222 2010

Email address
karami.t@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-09, 1400/06/18

Expected recruitment end date
2022-01-21, 1400/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of effect of preoperative oral carbohydrate on the blood glucose and hemodynamics in children under 3 years old undergoing elective inguinal surgeries

Public title
Evffect of preoperative oral carbohydrate on the blood glucose in children

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Elective surgeries American Society of Anesthesiologists (ASA) I and II Age less than 3 years

Exclusion criteria:
Emergency surgeries Having heart, lung and liver diseases Having metabolic diseases Having diabetes Glucose 6-phosphate deficiency

Age
To **3 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **207**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients, using random allocation software, were randomly divided into control (fasting) and intervention (preoperative oral carbohydrate) groups. By selecting the simple randomization method in the randomization box and entering the determined total sample size in this software, numbers were given to the patients and the patients were allocated into two groups according to computer-generated numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient is a child under 3 years old and has no information about the routine of receiving or not receiving carbohydrates before the operation and also the statistical analyzer will receive the data in code A and B for control and intervention groups, respectively.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
No. 30, Jahad Sq., Resalat St., Urmia University of Medical Sciences, Urmia

City
Urmia

Province
West Azarbaijan

Postal code
5715833631

Approval date
2021-05-26, 1400/03/05

Ethics committee reference number
IR.UMSU.REC.1400.058

Health conditions studied

1

Description of health condition studied
Blood glucose

ICD-10 code
R73

ICD-10 code description
Elevated blood glucose level

Primary outcomes

1

Description
Blood glucose

Timepoint
Before induction of anesthesia and during surgery and recovery

Method of measurement
Glucometer

Secondary outcomes

1

Description
Vomiting

Timepoint
At the time of induction of anesthesia and after withdrawal from anesthesia

Method of measurement
Obervation

2

Description
Heart rate

Timepoint
Every 5 minutes for 20 minutes

Method of measurement

Cardiac monitoring

3

Description
Mean arterial p[pressure
Timepoint
Every 5 minutes for 20 minutes
Method of measurement
Cardiac monitoring

Intervention groups

1

Description
Intervention group: In the intervention I group, 5 ml / kg of 20% dextrose solution made by Samen Pharmaceutical Company will be prepared orally for surgery in the pediatric surgery ward 2 hours before surgery,
Category
Treatment - Other

2

Description
Intervention group 2: In this group, 5 ml / kg drinking water will be prescribed two hours before surgery.
Category
Other

3

Description
Control group: This group will fast according to pre-surgery standards.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Shahid Motahari University Hospital
Full name of responsible person
Tohid Karami
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Tohid Karami
Position
Assistant professor
Latest degree
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Reporting of results as a published article
When the data will become available and for how long
After publishing of article
To whom data/document is available
Researchers
Under which criteria data/document could be used
As published article
From where data/document is obtainable
Corresponding author
What processes are involved for a request to access data/document
If necessary access to the data can be done through the e-mail address of the corresponding author that will be written in the published article.
Comments