

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Effect 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, Jihad 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

Observation

2

Description

Heart rate

Timepoint

Every 5 minutes for 20 minutes

Method of measurement

Cardiac monitoring

3

Description

Mean arterial p[ressure

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

Street address

No. 30, Jihad Sq., Resalat St., Urmia University of Medical Sciences, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5715833631

Phone

+98 44 3348 9752

Fax

+98 44 3345 7287

Email

karami.tohid@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

Jihad Sq., Resalat St., Uremia University of Medical Sciences, Uremia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5715833631

Phone

+98 44 3193 7224

Email

mohebbi_iraj@yahoo.co.uk

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

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

No. 30, Jihad Sq., Resalat st., Urmia University of Medical Sciences, Urmia

City

Urmia
Province
West Azarbaijan
Postal code
5715833631
Phone
+98 44 3193 7000
Fax
+98 44 3345 7287
Email
karami.tohid@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Tohid Karami
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
No. 30, Jihad Sq., Resalat st., Urmia University of
Medical Sciences, Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5715833631
Phone
+98 44 3193 7000
Fax
+98 44 3345 7287
Email
karami.tohid@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Tohid Karami
Position
Assistant professor
Latest degree

Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
No. 30, Jihad Sq., Resalat St., Urmia University of
Medical Sciences, Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5715833631
Phone
+98 44 3345 7287
Fax
+98 44 3345 7287
Email
karami.tohid@gmail.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

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