Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of the effect of preoperative oral carbohydrate on the pre and post-operative agitation in children undergoing elective herniorrhaphy

Protocol summary

Study aim

If preoperative oral carbohydrate has positive results in reducing pre and post-operative agitation in children, it will be recommended to use it as a routine guideline to reduce the agitation of children who are candidates for surgery.

Design

In this double-blind clinical trial study, 120 children were selected who aged between 6 months and 10 years, were candidates for elective herniorrhaphy and admitted to Motahhari Hospital during the first half of 2019 in Urmia . They were divided randomly into two intervention and control groups by random allocation software.

Settings and conduct

In this double-blind clinical trial study, 120 children were selected who aged between 6 months and 10 years, were candidates for elective herniorrhaphy and admitted to Motahhari Hospital during the first half of 2019 in Urmia . They were divided randomly into two intervention and control groups by random allocation software.

Participants/Inclusion and exclusion criteria

The children who were candidates for elective herniation, aged between 6 months and 10 years, ASA class I and II

Intervention groups

The children who were candidates for inguinal herniorrhaphy received oral carbohydrates.

Main outcome variables

Assessment of the level of children's agitation, probability of vomiting and aspiration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170516033992N1**
Registration date: **2020-08-26, 1399/06/05**
Registration timing: **retrospective**

Last update: **2020-08-26, 1399/06/05**
Update count: **0**

Registration date

2020-08-26, 1399/06/05

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

2019-07-23, 1398/05/01

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

2019-07-23, 1398/05/01

Actual recruitment end date

2019-11-21, 1398/08/30

Trial completion date

2020-02-19, 1398/11/30

Scientific title

Assessment of the effect of preoperative oral carbohydrate on the pre and post-operative agitation in children undergoing elective herniorrhaphy

Public title

Assessment of the effect of preoperative oral carbohydrate on agitation in children

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for inguinal hernia repair surgery Children aged between 6 month to 10 years

Exclusion criteria:

American Society of Anesthesiologists (ASA) above class II

Age

From **6 months** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will conduct based on permuted block randomization method. Each block will have capacity for 4 subjects. Then, within each block, subjects will be randomly assigned to intervention (n=60) or placebo (n=60). Random assignment will be done using a random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

Both of the patients participating in the study and the researcher were unaware of how individuals entered the study and control groups.

Placebo

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

Jahad Sq., Resalat St., Urmia University of Medical Sciences

City

Urmia

Province

West Azarbaijan

Postal code

5715833631

Approval date

2019-07-22, 1398/04/31

Ethics committee reference number

IR.UMSU.REC.1398.145

Health conditions studied

1

Description of health condition studied

Hernia

ICD-10 code

K41

ICD-10 code description

Femoral hernia

Primary outcomes

1

Description

Agitation in children

Timepoint

Assessment of the level of preoperative agitation and postoperative agitation at 5,15, 30 minutes

Method of measurement

Agitation assessment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 60 children in the intervention group consumed 5 ml / kg carbohydrate drink exactly 2 hours before the operation

Category

Treatment - Other

2

Description

Control group: 60 children in the intervention group consumed 5 ml / kg distilled water exactly 2 hours before the operation

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Urmia Shahid Motahari University Hospital

Full name of responsible person
Tohid Karami

Street address
Jahad Sq., Resalat St., Urmia University of Medical Sciences

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
Tohid Karami

Street address
Jahad Sq., Resalat st., Urmia University of Medical Sciences

City
Urmia

Province
West Azarbaijan

Postal code
5715833631

Phone
+98 44 3193 7000

Fax
+98 44 3345 7287

Email
karami.tohid@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Urmia 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
Jahad Sq., Resalat st., Urmia University of Medical Sciences

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

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Oroumia University of Medical Sciences

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West Azarbaijan

Postal code
5715833631

Phone
+98 44 3345 7287

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

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Tohid Karami

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Street address
Jahad Sq., Resalat St., Urmia University of Medical Sciences

City
Urmia

Province
West Azarbaijan

Postal code
5715833631

Phone
+98 44 3193 7000

Fax
+98 44 3346 9931

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
Individual data will be confidential and the results of the study will be published as an article.

When the data will become available and for how long
2020

To whom data/document is available
The article will be published internationally.

Under which criteria data/document could be used
There is no special condition.

From where data/document is obtainable
Internet

What processes are involved for a request to access data/document
Searching on the databases

Comments