

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Tohid Karami

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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

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Person responsible for updating data

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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

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