

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of oral carbohydrate on pain, postoperative nausea and vomiting in Children

Protocol summary

Summary

In a double-blind and , 60 children aged between 6 and 16 years candidate for elective herniorrhaphy during 2014-2015 enrolled the study. Patients were randomly divided into two groups. The first group, received 5 ml/kg of 12.5% CHO solution two hours before surgery, and the second group received similar volumes of plain water. After admission to the operating room, surgery is performed under general anesthesia. After the completion of surgery patients were transferred to the recovery room. Patients were kept in the recovery room for two hours and then moved to the ward. Patients received acetaminophen suppositories every 4 hours (10 mg/kg) for analgesia. Postoperative pain was measured 2, 6, 12 and 24 after the surgery using Visual Analog Scale (VAS). If the pain score was more than four, the patient received 1 mg/kg of intramuscular pethidine. The frequency of PONV and pain; 2, 6, 12 and 24 hours after the surgery as well as opioid consumption were recorded. Thirst and hunger (not at all=0, a little=2, moderately=4 and very much=6) at the time of admission to the operating room as well as the first request of food or water were recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201710318433N5**

Registration date: **2017-11-08, 1396/08/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-08, 1396/08/17

Registrant information

Name

Mohammad Reza Fazel

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0026

Email address

fazel_mr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University Of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral carbohydrate on pain, postoperative nausea and vomiting in Children

Public title

Effect of oral carbohydrate on pain, postoperative nausea and vomiting

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age 6-16 years old ;elective unilateral herniorrhaphy; Exclusion Criteria: history of diabetes; autoimmune disease; use of non-steroidal analgesics drugs

Age

From **6 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research & Technology, Kashan
University of Medical Sciences

Street address

Ghotbe Ravandi Blvd, 5th Km

City

Kashan

Postal code

8715988141

Approval date

2013-01-07, 1391/10/18

Ethics committee reference number

9167

Health conditions studied

1

Description of health condition studied

Acute pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

pain

Timepoint

2-6-12-24 hours

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

nausea and vomiting

Timepoint

2-6-12-24 hours

Method of measurement

Number of cases occurred

Intervention groups

1

Description

In the intervention group, patients received 5 ml/kg of 12.5% CHO solution two hours before surgery.

Category

Treatment - Drugs

2

Description

In the control group, patients received 5 ml/kg of plain water two hours before surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

shahid beheshti hospital

Full name of responsible person

Mohammad Reza Fazel

Street address

shahid beheshti hospital, Ghotbe Ravandi Blvd, 5th Km

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research & Technology, Kashan
University of Medical Sciences

Full name of responsible person

Gholam Ali Hamidi (Ph.D)

Street address

Ghotbe Ravandi Blvd, 5th Km

City
Kashan

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for Research & Technology, Kashan
University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Mohammad Reza Fazel

Position
Anesthesiologist

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty