Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of restrictive and liberal fluid therapy on Postoperative nausea and vomiting in pediatric tonsillectomy surgery

Protocol summary

Study aim
This investigation was planned to evaluate the effect of superhydration on reducing the incidence of postoperative nausea and vomiting after tonsillectomy surgery.

Design
This is a two arm parallel group randomized clinical trial with blinded postoperative care and outcome assessment in which 110 patients will be studied in 2 groups

Settings and conduct
This investigation will be performed in Besat Hospital, Hamadan. The person who care the patients and the person who analyze the data are blinded to group stratification. After induction of general anesthesia; infusion of the fluids will be started according to the patients' group. Incidence of nausea and vomiting and rescue antiemetic drug usage will be recorded at recovery and at 12 and 24 hours after surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: all of the ASA 1 (2-12yr) healthy children candidate for adenotonsillectomy Exclusion criteria: diabetes, antiemetic or psychotic drug usage during previous 24 hours, gastroesophageal reflux

Intervention groups
Intervention group: Infusion of lactated Ringer 30 cc/kg during surgery Control group: Infusion of lactated Ringer 10 cc/kg during surgery

Main outcome variables
Postoperative nausea and vomiting, dose of antiemetic drug used during the first 24 hours after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120118008768N9**
Registration date: **2019-03-17, 1397/12/26**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-17, 1397/12/26**
Update count: **0**

Registration date
2019-03-17, 1397/12/26

Registrant information

Name
Mahshid Nikooseresht

Name of organization / entity
Hamadan university of Medical Sciences, Faculty of Medicine

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-09, 1397/07/17

Expected recruitment end date
2019-09-22, 1398/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of restrictive and liberal fluid therapy on Postoperative nausea and vomiting in pediatric tonsillectomy surgery

Public title

Evaluation of the effect of superhydration on postoperative nausea and vomiting after tonsillectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy children aged between 2-12 yr Candidate for tonsillectomy

Exclusion criteria:

Refuse to sign the informed consent by the parents history of diabetes mellitus mental retardation obesity (body mass index N95th percentile for age and sex intake of antiemetic within 24 hours before surgery intake of psychoactive medication within 24 hours before surgery known gastroesophageal reflux. Inaccessibility of patient for follow-up

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with sealed envelope For this purpose 4 papers were prepared. The letter "I" for Internention was written on 2 papers and the letter "C" for Comparison was written on two another papers. All 4 sheets were placed in a drawer and for including each patient one sheet was pulled out. According to the letter on the sheet "I" or "C"; the patient was assigned to intervention (leg elevation) or control (supine position) group. All of the four sheets were re-turned to the drawer and this cycle will be continued to meet the calculated sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, the person who collects data and the person who analyzes the data are blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee of Ethics in Research, Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street, Hamadan

City

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Province

Hamadan

Postal code

65178

Approval date

2018-10-09, 1397/07/17

Ethics committee reference number

IR.UMSHA.REC.1397.467

Health conditions studied

1

Description of health condition studied

Nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

postoperative nausea and vomiting

Timepoint

in recovery room, 12 hours and 24 hours after surgery

Method of measurement

question from patient or parents

Secondary outcomes

1

Description

Requested antiemetic dose in first 24 hours after surgery

Timepoint

At first 24 hours after surgery

Method of measurement

Evaluation of patients file and recording in questionnaire

Intervention groups

1

Description

Intervention group: (superhydration) Ringer lactate infusion 30cc/kg at the time of operation

Category

Prevention

2

Description
Control group: Infusion of 10cc/kg Lactated Ringer during surgery
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Mahshid Nikooseresht
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Mahshid Nikooseresht
Position
Associate Professor of Anesthsiology, Fellowship of Pain managenent
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available