Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of reducing preoperative clear fluid fasting time on hemodynamic status and risk of aspiration in 2-6 years old children

Protocol summary

Study aim

evaluating the effect of reducing preoperative clear fluid fasting time on hemodynamic statue of a child before and after operation and evaluating the risk of pulmonary aspiration in 2 to 6 years old children

Design

clinical trial has a control group with a parallel group without blinding the research will be performed on 96 patients .excel will be used for randomization

Settings and conduct

96 patients enter the study after and are divided into case and control groups. Complete collection and examination is performed. Parents will be given a full explanation on how to keep children fasting. With the cooperation of surgeons and anesthesiologists, in Tabriz shohada hospital,the day before the operation, the parents will be explained that one hour before the operation, with the help of a nurse, 4ml / Kg of plain water will be given to the child. Patients will not receive intravenous fluids before surgery. When entering the operating room hemodynamic status, nausea and vomiting during induction or awakening of the patient and the appearance of any signs of aspiration will be recorded in the recovery phase and chest x-ray in case of signs of signs Will be obtained for pulmonary aspiration.

Participants/Inclusion and exclusion criteria

Including criteria 1.Children between 2-6 years old 2.Time of operation under 2 hours 3.Obtaining parents' satisfaction Excluding criteria 1.age below 2 years and over 6 years 2.parental dissatisfaction 3.operations over 2 hours 4.operations of gastrointestinal tract 5.history of special medications 6.history of a previous surgery 7.history of congenital anomalies 8.patients who undergo emergent surgeries

Intervention groups

Patients will receive 4ml/kg clear fluids one hour before entering operation room.Routin fasting time will be used in control group.

Main outcome variables

Signs of pulmonary aspiration;hemodynamic statue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220611055132N1**
Registration date: **2023-11-29, 1402/09/08**
Registration timing: **prospective**

Last update: **2023-11-29, 1402/09/08**
Update count: **0**

Registration date

2023-11-29, 1402/09/08

Registrant information

Name
Maryam Hejazi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 41 3386 1075
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hejazimaryam28@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-02-04, 1402/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the effect of reducing preoperative clear fluid fasting time on hemodynamic status and risk of aspiration in 2-6 years old children

Public title
The effect of reduced clear fluid fasting time on hemodynamic status and risk of pulmonary aspiration in children

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Children between 2-6 years old Time of operation under 2hours Obtaining parents' consent
Exclusion criteria:
age below 2 years and over 6 years parental dissatisfaction operations over 2 hours operations of gastrointestinal tract history of special medications history of a previous surgery history of congenital anomalies patients who undergo emergent surgeries

Age
From **2 years** old to **6 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Using a Computerized randomization with block diagram the studied patients will be divided into interventional group and control group to reduce bias.The block randomization method is designed to randomize subjects into groups that result in equal sample sizes. This method is used to ensure a balance in sample size across groups over time.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of medical science

Street address
Tabriz,Golshahr,Golha blvd,Omidfar alley,No.25,4th floor

City
Tabriz

Province
East Azarbaijan

Postal code
5167856961

Approval date
2023-10-23, 1402/08/01

Ethics committee reference number
IR.TBZMED.REC.1402.529

Health conditions studied

1

Description of health condition studied
In this study disease is not examined

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Hemodynamic statue

Timepoint
Preoperative-during surgery-post operative

Method of measurement
Non invasive monitoring of vital signs

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:They will receive 4ml/kg clear fluids(water) one hour before surgical operation

Category
Other

2

Description
Control group:The patients of Control group will receive regular fasting regime

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohada hospital

Full name of responsible person
Dr Naghi Abedini

Street address
Anesthesia Department -Second Flour-Medical College-Tabriz University of Medical Science-Golgasht St-Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Parviz Shahabi

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parvizshahabi@gmail.com

Grant name
0

Grant code / Reference number
0

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

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Naghi Abedini

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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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
Yes - There is 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
Title and more details about the data/document
0
When the data will become available and for how long
0
To whom data/document is available
0
Under which criteria data/document could be used
0
From where data/document is obtainable
0
What processes are involved for a request to access data/document
8
Comments