

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

##### Email address

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3334 1994

**Email**

Naghi26@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Parviz Shahabi

**Street address**

3rd Floor-No 2 Central Building-Tabriz University of  
Medical Science-University St-Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165665931

**Phone**

+98 41 3335 7310

**Email**

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

**Street address**

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3334 1994

**Email**

Naghi26@yahoo.com

**Person responsible for scientific 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

**Street address**

Anesthesia Department-2th floor-Medical College-  
Tabriz university of Medical science-Golgasht St-  
Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3334 1994

**Email**

Naghi26@yahoo.com

**Person responsible for updating data**

**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

**Street address**Anesthesia Department-Second Floor-Medical  
College-Tabriz University of Medical Science-Golgasht  
St-Tabriz**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 914 313 8038

**Email**

Naghi26@yahoo.com

**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**