

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of preoperative education with midazolam premedication in children anxiety reducing undergo adenotonsillectomy.

#### Protocol summary

##### Summary

**Objectives:** Due to multiplicity of adenotonsillectomy in children aged 2 to 10 years old in pediatric surgery centers, their anxiety increases complications of surgery and anesthesia. Furthermore patients' unawareness of surgical intervention and anesthesia adds to their stress. Premedication with Midazolam can decrease patients' anxiety. Similar results have been shown in the effectiveness of children's training about surgery and anesthesia before operation. The purpose of this study is to compare and survey the behavioral reactions in two groups of children receiving anesthesia guide booklet with child language and recipient of oral Midazolam.

**Design, Setting and conduct:** Methods: In this study, 48 children over the age of 7 and under adenotonsillectomy will be selected. They will be randomly allocated into two groups. Participants including major eligibility criteria: Included criteria: children over the age of 7; ASA I-II, adenotonsillectomy candidates. Excluded criteria: Surgical emergency; children with chronic illnesses; history of previous hospitalization; history of medication; delayed growth in children ; illiterate parents.

**Intervention:** The first group in preoperative visit, a booklet about surgery and anesthesia understandable to the general public with simplistic sketches for the children is offered. The second group will receive 0.5 mg per kg of body weight Midazolam half an hour before entering the operation room. main outcome measures (variables): Anxiety, Drug side effects.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012112111554N1**

Registration date: **2013-03-09, 1391/12/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-03-09, 1391/12/19

##### Registrant information

###### Name

Afshin Davari

###### Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

###### Phone

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2012-12-21, 1391/10/01

##### Expected recruitment end date

2013-04-21, 1392/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of preoperative education with midazolam premedication in children anxiety reducing undergo adenotonsillectomy.

##### Public title

Preoperative education effect on anxiety reduction in children.

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion Criteria:children over 7 years; ASA I-II, adenotonsillectomy candidate. Exclusion criteria: Surgical emergency; children with chronic illness; history of previous hospitalization; history of drug use; delayed growth in children ; having illiterate parents.

**Age**

From **7 years** old to **15 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****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**

Tabriz University of Medical Sciences Ethical Committee

**Street address**

Tabriz University of Medical Sciences, Golgasht st, Azadi st

**City**

Tabriz

**Postal code****Approval date**

2012-07-30, 1391/05/09

**Ethics committee reference number**

9190

**Health conditions studied****1****Description of health condition studied**

Anxiety

**ICD-10 code**

F 93.0

**ICD-10 code description**

Separation anxiety disorder of childhood.

**Primary outcomes****1****Description**

Anxiety

**Timepoint**

Anxiety in these patients will be measured before their entry into the operating room.

**Method of measurement**

By the STAIC questionnaire(state trait anxiety inventory for children).

**Secondary outcomes****1****Description**

Drug side effects.

**Timepoint**

During 24 hours after drug administration.

**Method of measurement**

By questionnaire.

**Intervention groups****1****Description**

Group A: 0.5 mg per Kg oral midazolam with 20-30 ml water in 20-30 minutes before surgery.

**Category**

Prevention

**2****Description**

Group B (Training group ): In preoperative visit; a booklet about surgery and anesthesia understandable to the general public with a simple and understandable pictures for the children offered.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Dr Afshin Davari

**Street address**

Imam Khomeini Hospital, Atee st, Jeddi st

**City**

Ardabil

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Seyed Kazem Shakouri

**Street address**

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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**

Vice chancellor for research, Tabriz 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**

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**Full name of responsible person**

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## Person responsible for updating data

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## 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*