

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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.

Last update:

Update count: **0**

Registration date

2013-03-09, 1391/12/19

Registrant information

Name

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Name of organization / entity

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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.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012112111554N1**

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

Registration timing: **registered_while_recruiting**

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

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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

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Vice chancellor for research, Tabriz University of Medical Sciences, Golgasht st, Azadi st, Tabriz

City

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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

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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