Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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