

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of reducing the anxiety of mothers using Atenolol on the anxiety of children undergoing surgery

Protocol summary

Study aim

Determining the effect of reducing maternal anxiety using Atenolol on the level of anxiety of children who are candidates for surgery in hospital

Design

Clinical trial with two groups case and control, 30 children in each group with parallel groups, double-blind, Simple randomization, Demographic profile, Spielberger Anxiety Inventory and the Modified-Yale preoperative anxiety scale questionnaire will be used to collect data.

Settings and conduct

The study would be held in Moradi Hospital in Rafsanjan University of Medical Sciences, Rafsanjan, Iran, Two randomized groups: (intervention Group) The Mothers of children who will be undergoing surgery are going to be given atenolol to reduce their anxiety. (control group) receiving placebo. It is double blind, participants and investigator will not be aware of the intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion: Children 10-3 years old Candidate for tonsillectomy, No chronic disease, Having a mother at the time of admission and hospitalization, Not having any previous experience of surgery, No history of central nervous system diseases and mental illnesses. Exclusion: Mother's unwillingness to participate in research contraindication of the use of Atenolol in the mother Refusal to use Atenolol Being non-Iranian

Intervention groups

Treatment group: Mothers of children in the treatment group, will use Atenolol in a single dose, Stat50 mg (orally) the night before surgery. Control group will be taking placebo. Atenolol-like placebo will be used in dark packaged and coded envelopes to blind participants and investigators.

Main outcome variables

Anxiety of children candidates for surgery before induction of anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190128042525N5**

Registration date: **2021-01-27, 1399/11/08**

Registration timing: **prospective**

Last update: **2021-01-27, 1399/11/08**

Update count: **0**

Registration date

2021-01-27, 1399/11/08

Registrant information

Name

Gholamreza Bazmandegan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 0185

Email address

clinical.research@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-28, 1399/12/10

Expected recruitment end date

2021-08-01, 1400/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of reducing the anxiety of mothers using Atenolol on the anxiety of children undergoing surgery		Name of ethics committee Ethics committee of Rafsanjan University of Medical Sciences	
Public title The effect of reducing the anxiety of mothers using Atenolol on the anxiety of children undergoing surgery		Street address Ali Ibn Abitaleb Square	
Purpose Prevention		City Rafsanjan	
Inclusion/Exclusion criteria Inclusion criteria: Age 3-10 years No chronic disease (cancer, liver disease, kidney) Good hearing and ability to speak Having age-appropriate cognitive abilities Having a mother at the time of admission and hospitalization Not having any previous experience of surgery No history of central nervous system diseases and mental illnesses Maternal anxiety Exclusion criteria: Mother's unwillingness to participate in research Prohibitions of Atenolol use in the mother Refusal to use Atenolol Being non-Iranian		Province Kerman	
		Postal code 7717937555	
		Approval date 2020-12-02, 1399/09/12	
		Ethics committee reference number IR.RUMS.REC.1399.208	
Health conditions studied			
<u>1</u>			
Description of health condition studied Anxiety			
ICD-10 code F06.4			
ICD-10 code description Anxiety disorder due to known physiological condition			
Primary outcomes			
<u>1</u>			
Description Effects of reducing maternal anxiety using Atenolol on the level of anxiety in children of surgical candidates			
Timepoint The night before surgery			
Method of measurement 1- Demographic profile questionnaire, 2- Children's Anxiety Scale (Modified-Yale Preoperative Anxiety Scale)			
Secondary outcomes empty			
Intervention groups			
<u>1</u>			
Description Intervention group 1: Mothers of children will be given, single dose of ethanlolol, Stat 50 mg (orally) the night before surgery			
Category Prevention			
<u>2</u>			
Description Control group: an atenolol-like placebo will be used in dark packaged and coded envelopes			
Category Placebo			

Recruitment centers

1

Recruitment center

Name of recruitment center

Moradi Hospital

Full name of responsible person

Farshid Farahbakhsh

Street address

Shohada Street, Moalem Street

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

Rafsanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Rafsanjan University of Medical Sciences

Full name of responsible person

Farshid Farahbakhsh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available