

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of Sedative effect of Midazolam and Gabapentin in Pre-Tonsillectomy in Pediatric

Protocol summary

Study aim

1- Comparison of mask acceptance in children undergoing tonsillectomy in two groups of gabapentin and midazolam compared to control group 2- Comparison of changes in mean arterial blood pressure in children undergoing tonsillectomy in two groups of gabapentin and midazolam compared to control group. 3- Comparison of parental separation status in pediatric surgical candidates 4- Comparison of the incidence of amnesia in children undergoing tonsillectomy in two groups of gabapentin and midazolam compared to the control group. 5- Comparison of the incidence of respiratory weakness in children undergoing tonsillectomy in two groups of gabapentin and midazolam compared to the control group.

Design

The sample size was 108 people with design effect equal 0.3, 5 percent error and 80 percent power using G-power software. Therefore, 36 patients will be included in the study in each group.

Settings and conduct

Matini Hospital. This study is a double blind clinical trial. In this study, one hundred and eighty three to twelve year old children who are candidates for tonsillectomy who will be referred to Matini Hospital of Kashan in 2019 will be enrolled in this study by simple sampling method.

Participants/Inclusion and exclusion criteria

All 3-12 year-old children undergoing tonsillectomy are referred to Matini Hospital of Kashan.

Intervention groups

1- Gabapentin group received 12.5 mg/kg oral syrup 60 minutes before entering the operating room for the baby. 2- Midazolam 0.5 mg / kg oral dose administered to the infant 60 minutes prior to admission to the operating room 3- The third group received distilled water as the placebo group

Main outcome variables

Proper use of anti-anxiety drugs with limited side effects can minimize anxiety and restlessness in children and

minimize side effects after surgery and anesthesia in children.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191103045320N1**

Registration date: **2019-12-12, 1398/09/21**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-12, 1398/09/21**

Update count: **0**

Registration date

2019-12-12, 1398/09/21

Registrant information

Name

Mohammad Shabani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 4422 0704

Email address

mohammadshabaniiii77@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-26, 1398/09/05

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Sedative effect of Midazolam and Gabapantin in Pre-Tonsillectomy in Pediatric

Public title

Effect of Gabapantin versus Midazolam in Tonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children aged 3 to 12 years Candidate for tonsillectomy surgery Referred to Matini Hospital

Exclusion criteria:

Children with a history of allergy to any of the medications taken Children who themselves or their parents refuse to take the drug They had a history of using drugs affecting the central nervous system They had diseases affecting the central nervous system They needed emergency surgery It was estimated that their surgery would last more than one hour

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Sample size was 108 people with design effect = 0.3, 5% error and 80% power using G-power software. Therefore, 36 patients will be included in the study in each group

Blinding (investigator's opinion)

Triple blinded

Blinding description

1- Parents were required to participate in the study and the patient was not aware of the intervention. 2- The container containing the drugs and placebo was marked with the letters A, B, C, and was also listed on the checklist for information. 3- The data analyzer also analyzed the data according to the letters A, B and C

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kashan University of Medical Sciences

Street address

5 km Ravandi pole

City

kashan

Province

Isfahan

Postal code

8715973474

Approval date

2019-10-20, 1398/07/28

Ethics committee reference number

IR.KAUMS.REC.1398.043

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

Tonsilectomy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Age, gender, weight, temperature, heart rate, respiratory rate, systolic blood pressure, diastolic blood pressure, headache, mask acceptance, parental separation, respiratory weakening, chills, double vision, forgetfulness, bleeding, nausea, vomiting

Timepoint

Before prescribing medication, during induction of anesthesia, recovery, discharge from operating room

Method of measurement

Age (year), gender (male and female), weight (kg), temperature (degree C), heart rate (number of minutes), respiratory rate (number of minutes), systolic blood pressure (mmHg) , Diastolic blood pressure (mmHg), headache (yes or no), mask acceptance (no problem or no problem), parental separation (easy or difficult), respiratory weakness (oxygen saturation), chills (yes or no), Double vision (yes or no), forgetfulness (yes or no), bleeding (yes or no), nausea (yes or no), vomiting (yes or no)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One Gabapentin dose of 12.5 mg / kg oral 60 min before surgery - Midazolam 0.5 mg / kg oral 60 min before surgery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Matini Hospital

Full name of responsible person

Mohammad Ali Sadati

Street address

Kashan Amir Kabir Ave.

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Province

Isfahan

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8719674591

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Ali Sadati

Street address

Kashan five kilometers from Ravandi hospital next to Shahid Beheshti Hospital

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Isfahan

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Fax

+98 31 5546 4950

Email

info@kaums.ac.ir

Web page address

<http://kaums.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Shabani

Position

Undergraduate Student of Anesthesiology

Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Ali Sadati

Position

Anesthesiologist Faculty member

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

After this example, the selected samples and options are possible in the method

When the data will become available and for how long

Ten months

To whom data/document is available

Executor and supervisor of the project

Under which criteria data/document could be used

If necessary, review information or use it in national surveys

From where data/document is obtainable

To the presenters of the plan

What processes are involved for a request to access data/document

Once approved by the Ethics Committee of the Vice President of Technology Research at the University, access to the documentation will be available

Comments