

# 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)

##### Phone

+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.

#### City

Kashan

#### Province

Isfahan

#### Postal code

8719674591

#### Phone

+98 31 5534 2020

#### Fax

#### Email

mohammadshabaniii77@gmail.com

#### 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

#### City

Kashan

#### Province

Isfahan

#### Postal code

8715973474

#### Phone

+98 31 5544 3022

#### 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

#### Street address

Razi Street of Shahid Mahmoud Ebrahimi Alley

#### City

Kashan

#### Province

Isfahan

#### Postal code

37911-94955

#### Phone

+98 86 4422 0704

#### Email

mohammadshabaniii77@gmail.com

## 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

#### Street address

Kashan, Shahid Rajaie Street, Madani Street

#### City

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#### Province

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**Postal code**  
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dr.m.a.saadati@gmail.com

## Person responsible for updating data

### 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  
**Street address**  
Kashan, Shahid Rajaie Street, Madani Street  
**City**  
Kashan  
**Province**  
Isfahan  
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87137-5954  
**Phone**  
0355446251  
**Email**  
dr.m.a.saadati@gmail.com

## 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