

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of gabapentin and acetaminophen suspension on postoperative pain after adenotonsillectomy

#### Protocol summary

##### Summary

The purpose of this study was comparison effect of gabapentin and sup of acetaminophen in control of postoperative pain and nausea and vomiting. The main inclusion criteria included all children 7-15 years old candidate for adenotonsillectomy surgery and with recurrent and chronic tonsillitis, and exclusion criteria included history of seizure and gabapentin usage and taking pain killers in last 24 hours. The patients divided in to 30 member groups. In first groups children received 10/mg/kg, gabapentin 2 hour before anesthesia and second group received acetaminophen after maintenance of anesthesia. Both groups anesthetized in same manner then before induction of anesthesia and in 2,4,6,12,24 hour after operation both group were studied for existence of nausea and vomiting, types of drugs used, their dosage and degree of pain. Outside following time intervals if patients were complaining for pain or nausea and vomiting they were treated according to protocol. Patients were monitored for vital signs and respiratory after operation, and in case of hypotension there were treated by ephedrine and in case of respiratory depression they received oxygen by Ambu bag and ventilation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016102115963N7**  
Registration date: **2017-02-01, 1395/11/13**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-01, 1395/11/13

#### Registrant information

##### Name

Soudabeh Haddadi

##### Name of organization / entity

Guilan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13332383068

##### Email address

so\_haddadi@gums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Guilan University of Medical Sciences, Vice Chancellor for Research

#### Expected recruitment start date

2016-10-31, 1395/08/10

#### Expected recruitment end date

2017-08-01, 1396/05/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of gabapentin and acetaminophen suspension on postoperative pain after adenotonsillectomy

#### Public title

A survey comparing effect of gabapentin and acetaminophen suspension on postoperative pain after tonsil removal surgery in children receiving these drugs

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria : 7-15 year old child candidate for adenotonsillectomy; Recurrent tonsillitis; chronic

tonsillitis; Obstructive sleep apnea; Breathing with open mouth; Snoring and dysphagia Exclusion criteria : Known allergy to gabapentin and acetaminophen ; History of seizure and gabapentin usage; Renal or hepatic dysfunction; Usage of analgesic in last 24 hours; Opioid addiction; Known G6PD deficiency; Diarrhea and dehydration; Bleeding abnormality; operation lasting more than 90 min

#### Age

From **7 years** old to **15 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Guilan University of Medical Science

##### Street address

Vice-Chancellor for Research Building, Opposite of SepahBank, Shahid Beheshti Blvd, Rasht

##### City

Rasht

##### Postal code

#### Approval date

2016-08-13, 1395/05/23

#### Ethics committee reference number

IR.GUMS.REC.1395.157

## Health conditions studied

### 1

#### Description of health condition studied

Acute tonsillitis

#### ICD-10 code

J03

#### ICD-10 code description

Acute tonsillitis

## Primary outcomes

### 1

#### Description

Postoperative pain

#### Timepoint

2,4,6,12,24 hour after surgery

#### Method of measurement

Visual analog score

## Secondary outcomes

### 1

#### Description

Nausea and vomiting

#### Timepoint

2,4,6,12,24 hour after operation

#### Method of measurement

Based on asking patients in time intervals

## Intervention groups

### 1

#### Description

Control group: received acetaminophen after maintenance of anesthesia. Both groups anesthetized in same manner

#### Category

Treatment - Drugs

### 2

#### Description

Interventional group: received gabapentin 10mg/kg 2 hour before anesthesia

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amiralmomenin Hospital

##### Full name of responsible person

Dr Sudabeh Haddadi

##### Street address

Amiralmomenin Hospital, 17 Shahrivar St

##### City

Rasht

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Guilan University of Medical Science, Vice Chancellor for Research

**Full name of responsible person**

Susan Komaee

**Street address**

Vice-Chancellor for Research Building, Opposite of SepahBank, Shahid Beheshti Blvd, Rasht

**City**

Rasht

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Guilan University of Medical Science, Vice Chancellor for Research

**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

**Contact****Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Dr Soudabeh Haddadi

**Position**

Professor

**Other areas of specialty/work****Street address**

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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### Person responsible for updating data

**Contact****Name of organization / entity**

Guilan University of Medical Sciences

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Professor

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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*