

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### The effect of intravenous ketamine plus paracetamol versus intravenous paracetamol alone on postoperative pain, nausea and vomiting after pediatric adenotonsilectomy: a triple blinded randomized clinical trial

#### Protocol summary

##### Summary

**Objectives:** To assess the effect of intravenous ketamine plus paracetamol versus intravenous paracetamol alone on postoperative pain, nausea and vomiting after pediatric adenotonsilectomy. **Design:** A triple blinded randomized clinical trial. **Setting and conduct:** All eligible patients who are candidate for elective adenotonsilectomy and will refer to the Beasat Hospital during the study period will be enrolled in to the trial. **Inclusion criteria:** (a) 3 to 12 years old; (b) candidate for elective adenotonsilectomy; having one or two criteria based on Physical Status Classification American Society of Anesthesiologists (ASA) **Exclusion criteria:** (a) history of psychiatric disease; (b) using analgesic within 24 hours before surgery; (c) sensitivity to ketamine or acetaminophen; (d) using cautery for hemostasis. **Intervention:** Intravenous ketamine 0.25 mg/kg (2 ml) single dose plus intravenous acetaminophen 15 mg/kg single dose, 15 min before the end of surgery and every 6 hours until 24 hours after surgery. **Control:** Intravenous normal saline 2 ml single dose plus intravenous acetaminophen 15 mg/kg single dose, 15 min before the end of surgery and every 6 hours until 24 hours after surgery. **Primary outcome:** (a) Pain severity at 0.5, 6, 12, and 12 hours after surgery based on the CHEOPS Pain Score; (b) Number of nausea and vomiting at 0.5, 6, 12, and 12 hours after surgery based on clinical observation. **Secondary outcome:** The duration of time per min after surgery to using the first narcotic based on medical record.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201402179014N25**  
Registration date: **2014-05-26, 1393/03/05**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-05-26, 1393/03/05

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan  
University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice-chancellor for Research the Technology, Hamadan  
University of Medical Sciences

##### Expected recruitment start date

2014-06-22, 1393/04/01

##### Expected recruitment end date

2015-06-21, 1394/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of intravenous ketamine plus paracetamol

versus intravenous paracetamol alone on postoperative pain, nausea and vomiting after pediatric adenotonsilectomy: a triple blinded randomized clinical trial

#### Public title

The effect of intravenous ketamine plus paracetamol versus intravenous paracetamol alone on postoperative pain, nausea and vomiting after pediatric adenotonsilectomy

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: (a) 3 to 12 years old; (b) candidate for elective adenotonsilectomy; having one or two criteria based on Physical Status Classification American Society of Anesthesiologists (ASA) Exclusion criteria: (a) history of psychiatric disease; (b) using analgesic within 24 hours before surgery; (c) sensitivity to ketamine or acetaminophen; (d) using cautery for hemostasis.

#### Age

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

#### Gender

Male

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **98**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

Randomization: Using balance blocks randomization with block of four. Blinding: The drugs are prescribed during surgery hence the patients will not aware of the type of medications. Furthermore, the anesthesiologist who will assess the effect of the intervention will be aware of the coding of the intervention and control groups. In addition, the analyzer will not aware of the coding either. Therefore, the trial will be run triple blinded.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

#### Street address

Vice-chancellor of Research the Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

#### City

Hamadan

#### Postal code

6517838695

#### Approval date

2014-05-17, 1393/02/27

#### Ethics committee reference number

P/16/35/9/709

## Health conditions studied

### 1

#### Description of health condition studied

Pain in throat

#### ICD-10 code

R07.0

#### ICD-10 code description

Pain in throat

### 2

#### Description of health condition studied

Nausea and vomiting

#### ICD-10 code

R11

#### ICD-10 code description

Nausea and vomiting

## Primary outcomes

### 1

#### Description

Pain severity

#### Timepoint

at 0.5, 6, 12, and 12 hours after surgery

#### Method of measurement

based on the CHEOPS Pain Score

### 2

#### Description

Number of nausea and vomiting

#### Timepoint

at 0.5, 6, 12, and 12 hours after surgery

#### Method of measurement

based on clinical observation

## Secondary outcomes

### 1

#### Description

The duration of time to use the first narcotic

#### Timepoint

per min after surgery

#### Method of measurement

based on medical record

## Intervention groups

### 1

#### Description

Intravenous ketamine 0.25 mg/kg (2 ml) single dose plus intravenous acetaminophen 15 mg/kg single dose, 15 min before the end of surgery and every 6 hours until 24 hours after surgery.

#### Category

Treatment - Drugs

### 2

#### Description

Intravenous normal saline 2 ml single dose plus intravenous acetaminophen 15 mg/kg single dose, 15 min before the end of surgery and every 6 hours until 24 hours after surgery.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Beasat Hospital

##### Full name of responsible person

Dr Hossein Kimiaei

##### Street address

Beasat Hospital, Shahed Square

##### City

Hamadan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences

##### Full name of responsible person

Dr Saeid Bashirian

##### Street address

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### City

Hamadan

#### 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 the Technology, Hamadan  
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

#### Contact

##### Name of organization / entity

Beasat Hospital

##### Full name of responsible person

Dr Lida Noori

##### Position

Resident of Anesthesiology

##### Other areas of specialty/work

##### Street address

Beasat Hospital, Shahed Square

##### City

Hamadan

##### Postal code

##### Phone

+98 918 341 6392

##### Fax

##### Email

Dr.lidanori@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Beasat Hospital

##### Full name of responsible person

Dr Hossein Kimiaei

##### Position

Anesthesiologist

##### Other areas of specialty/work

##### Street address

Beasat Hospital, Shahed Square

##### City

Hamadan

##### Postal code

##### Phone

+98 81 1341 6392

##### Fax

##### Email

kimiaei@umsha.ac.ir

##### Web page address

## Person responsible for updating data

#### Contact

## **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*