

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Comparison of rehydration and ketamine on postoperative pain in children undergoing adenotonsillectomy in shahid Mohammadi hospital of Bandar Abbas at 2014

#### Protocol summary

##### Summary

Aim of this study: Comparing the effects of fluid administration with intravenous ketamin on postoperative pain after adenotonsillectomy in children. Type of study: Randomized, double blind clinical trial. Population of study: Eighty infants who are candidate for adenotonsillectomy operation in Shahid Mohammadi Hospital Inclusion criteria: age 5 - 8 years; ASA I-II Exclusion criteria: Systemic disease; Metabolic disease; Endocrine disease; mental retardation; failure to thrive; history of allergic disease; tonsilar abscess; hypertension; chronic pain; individuals who are on treatment for chronic pain Method: After informing the parents about the investigation and obtaining consent the infants will be allocated randomly (drawing random cards method) into either group ketamine (K) or fluid therapy (NS). Five minutes before anesthesia induction for group K intravenous ketamine (0.2 mg/kg) and for group NS normal saline (10 cc/kg) will be administered. Induction of anesthesia is provided by fentanyl (2 microgm/kg), lidocaine (1 mg/kg) and sodium thiopental (5 mg/kg) which are followed by tracheal intubation. Anesthesia maintenance will be by oxygen and nitrous oxide (50/50%) with propofol infusion (100 microgram/kg/min). The patients will be evaluated during their recovery by the visual analogue scale (0 - 100 points) at 0, 2, 6, 12 and 24 hours after the end of operation. The level of sedation will be assessed by Ramsey-H scoring system (1-6 points). The data will be collected by a student who is unaware of the type of drug applied during the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015071318091N3**

Registration date: **2016-04-14, 1395/01/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-04-14, 1395/01/26

##### Registrant information

###### Name

Fekrat Fereydoon

###### Name of organization / entity

Hormozgan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 76 3334 4009

###### Email address

fereydoon.fekrat@hums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

governmental resources of Shahid Mohammadi Hospital, Hormozgan University of Medical Sciences

##### Expected recruitment start date

2015-07-23, 1394/05/01

##### Expected recruitment end date

2015-10-23, 1394/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of rehydration and ketamine on

postoperative pain in children undergoing adenotonsillectomy in shahid Mohammadi hospital of Bandar Abbas at 2014

#### Public title

comparing the effects of fluid therapy and ketamin drug administration on pain after adeniod and tonsilar

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: age 5 - 8 years; ASA I-II Exclusion criteria: Systemic disease; Metabolic disease; Endocrine disease; mental retardation; failure to thrive; history of allergic disease; tonsilar abscess; hypertension; chronic pain; individuals who are on treatment for chronic pain

#### Age

From **5 years** old to **8 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **80**

#### 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

Deputy for Research, and Medical Ethics Committee of Hormozgan University of Medical Sciences

##### Street address

Joomhoori Islami Blvd., Shahid Mohammadi Hospital

##### City

Bandar Abbas

##### Postal code

7919915519

##### Approval date

2010-09-23, 1389/07/01

##### Ethics committee reference number

HUMS.REC.1394.63

## Health conditions studied

### 1

#### Description of health condition studied

Hypertrophy of tonsils with hypertrophy of adenoids disease

#### ICD-10 code

J35.3

#### ICD-10 code description

Hypertrophy of tonsils with hypertrophy of adenoids

## Primary outcomes

### 1

#### Description

to decrease the pain level after tonsilectomy

#### Timepoint

after the end of tonsilectomy

#### Method of measurement

Visual Analogue Scale: VAS

## Secondary outcomes

### 1

#### Description

nausea and vomiting

#### Timepoint

In recovery at 0, 2, 6, 12, 24 hours after adenotonsilectomy operation

#### Method of measurement

Descriptive

### 2

#### Description

Sedation condition

#### Timepoint

In recovery at 0, 2, 6, 12, 24 hours after adenotonsilectomy operation

#### Method of measurement

Ramsey-H score

## Intervention groups

### 1

#### Description

Five minutes before anesthesia induction for group K intravenous ketamine (0.2 mg/kg) will be administered. Induction of anesthesia is provided by fentanyl (2 microgm/kg), lidocaine (1 mg/kg) and sodium thiopental (5 mg/kg) which are followed by tracheal intubation. Anesthesia maintenance will be by oxygen and nitrous oxide (50/50%) with propofol infusion (100 microgram/kg/min).

#### Category

Treatment - Drugs

## 2

### Description

Five minutes before anesthesia induction for group NS normal saline (10cc/kg) will be administered. Induction of anesthesia is provided by fentanyl (2 microgm/kg), lidocaine (1 mg/kg) and sodium thiopental (5 mg/kg) which are followed by tracheal intubation. Anesthesia maintenance will be by oxygen and nitrous oxide (50/50%) with propofol infusion (100 microgram/kg/min).

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Mohammadi Hospital

##### Full name of responsible person

Alireza Abdolazade Baghaee

##### Street address

Joomhoori Islami Blv., Shahid Mohammadi Hospital

##### City

Bandar Abbas

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hormozgan University of Medical Sciences

##### Full name of responsible person

Abdulazim Nejatizadeh

##### Street address

Joomhoori Islami Blv., Deputy of Research Center,  
Shahid Mohammadi Hospital

##### City

Bandar Abbas

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Hormozgan 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

Shahid Mohammadi Hospital

#### Full name of responsible person

Alireza Abdolazade Baghaee

#### Position

Assistant Professor of Anesthesiology and Intensive care - Fellowship of pain

#### Other areas of specialty/work

#### Street address

Joomhoori Islami Blv., Deputy of Research Center,  
Shahid Mohammadi Hospital

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#### Phone

+98 76 3334 5009

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#### Email

bagha\_ar@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Hormozgan University of Medical Sciences

#### Full name of responsible person

Alireza Abdolazade Baghaee

#### Position

Assistant Professor of Anesthesiology and Intensive care - Fellowship of Pain

#### Other areas of specialty/work

#### Street address

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Hormozgan University of Medical Sciences

#### Full name of responsible person

Fereydoon Fekrat

#### Position

Specialist in Anesthesiology and Intensive care

#### Other areas of specialty/work

#### Street address

Joomhoori Islami Blv., Shahid Mohammadi Hospital

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**Fax**  
**Email**  
**Web page address**

## 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*