

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Sep 2026

### Comparison the effect of oral mixture of midazolam and ketamin with oral mixture of meperidine and cholral hydrate in agitation and post operative pain in pediatric patients undergoing tonsillectomy

#### Protocol summary

##### Summary

In this study we aim to compare the effect of oral mixture of midazolam and ketamine with oral mixture of meperidine and chloral hydrate in calmness of pediatrics during going to operation room, emergence agitation following operation ,severity of post operative pain and also complications like nausea and vomiting will be compared too.64 pediatrics patients who will be candidate and have study's criteria will be allocated by simple randomization in the two 32 pediatrics groups. In the group one pediatrics will received oral mixture of midazolam5 mg/kg with ketamine 5mg/kg 30 min before going to operation and in group two, pediatrics will received oral mixture mepeidine 1.5 mg/kg and chloral hydrate50 mg/kg 30 min before going to operation.Then pediatrics calmness during going to operation, postoperative pain and agitation will be recorded and will be compared. Also, complications such as nausea and vomiting will be recorded and compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015111611662N8**

Registration date: **2015-12-17, 1394/09/26**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-12-17, 1394/09/26

##### Registrant information

###### Name

Mohammad Ali Sahmeddini

**Name of organization / entity**

Shiraz University Of Medical Sciences

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Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences .

##### Expected recruitment start date

2015-10-23, 1394/08/01

##### Expected recruitment end date

2016-02-20, 1394/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of oral mixture of midazolam and ketamin with oral mixture of meperidine and chloral hydrate in agitation and post operative pain in pediatric patients undergoing tonsillectomy

##### Public title

Effect of oral mixture of midazolam and ketamin with oral mixture of meperidine and chloral hydrate on calmness and post operative pain in pediatric tonsillectomy surgery.

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

64 pediatrics patients who will be candidate for elective

tonsillectomy under general anesthesia will be enrolled in this study. Exclusion criteria are: emergency surgery; history of cardiopulmonary disorders; hypersensitivity to study's drugs; liver disease; kidney disease and history of convulsion.

#### Age

From **3 years** old to **8 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: **64**

#### 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

Shiraz Medica School Research Ethic Committee

##### Street address

Shiraz Medical School -Zand Blv

##### City

Shiarz

##### Postal code

197871345

#### Approval date

2015-09-23, 1394/07/01

#### Ethics committee reference number

IR.sums.med.rec.1394.351

## Health conditions studied

### 1

#### Description of health condition studied

pain following tonsillectomy

#### ICD-10 code

R07.0

#### ICD-10 code description

Pain in throat

## Primary outcomes

### 1

#### Description

post operative pain

#### Timepoint

Every hour during first 6 hours post operation

#### Method of measurement

Backer-Wong-faces pain scale

### 2

#### Description

postoperative agitation

#### Timepoint

after awakening in recovery room

#### Method of measurement

according to this scale: 1.Asleep ;2. Awake but comfort ;3.Agitate ; 4.severly agitate and difficult to calm

### 3

#### Description

calmness during going to operatin theater

#### Timepoint

During seperation from parents and going to operation theater

#### Method of measurement

according to this scale: 1.Full awake-calm ; 2. crying ; 3. violent movement ; 4. Asleep

## Secondary outcomes

### 1

#### Description

Nausea and Vomiting

#### Timepoint

Every one hour during first postoperative 6 hr

#### Method of measurement

Nausea is defined as urge to vomiting without ejection of the contents of the stomach through the mouth, Vomiting is defined as to eject of the contents of the stomach through the mouth, usually in a series of involuntary spasmic movements.

## Intervention groups

### 1

#### Description

In the group one pediatrics will be received oral mixture midazolam and ketamine mg/kg 30 min before going to operation room.

#### Category

Treatment - Drugs

### 2

#### Description

in the 2nd group pediatrics will be received oral mixture

of meperidine mg/kg and chloral hydrate mg/kg 30 min before operation

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Khalili training and medical center

**Full name of responsible person**

Mohamma Ali Sahmeddini

**Street address**

Khalili Avenue

**City**

Shiraz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice-Chancellery of Research and Technology

**Full name of responsible person**

Dr Seyed Basir Hashemi

**Street address**

Shiraz University Of Medical Sciences

**City**

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice-Chancellery of Research and Technology

**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**

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**Full name of responsible person**

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**Position**

Fellowship Of Organ Transplantation Anesthesia

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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*