

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Study of the association of various ketamine doses with vomiting in children requiring sedation in the emergency department

#### Protocol summary

##### Study aim

Determination of the incidence of vomiting in children receiving ketamine. Determination of the relationship between the dose of ketamine and vomiting  
Determination of the relationship between the administration of ketamine and vomiting

##### Design

Clinical trials without control groups, community-based and action-oriented, non-randomized, four groups with different doses

##### Settings and conduct

some previous studies reported important adverse events associated with ketamine such as hypoxia, laryngospasm, apnea, vomiting, and emergency reactions. Therefore, we evaluated doses of Ketamine associated vomiting (KAV) in children require sedation, who were referred for diagnostic or treatment services in Ahvaz golestan hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who require sedation for therapeutic or diagnostic process (reduction of fractures, CT scan, stitches, etc.) aged between 4 months to 13 years  
Exclusion criteria: patients less than 3 months and more than 13 years patients who had vomiting before sedation patients who did not receive single-dose medication patients who suspected increased ICP asthma or previous adverse reaction to ketamine cardiovascular diseases or hypertension airway tract infections porphyria

##### Intervention groups

Patients in first group will receive ketamine via intravenous with dosage of 1 mg/kg  
Patients in Second group will receive ketamine via intravenous with dosage of 2 mg/kg  
Patients in Third group will receive ketamine via intramuscular with dosage of 3 mg/kg  
Patients in Fourth group will receive ketamine via intramuscular with dosage of 5 mg/kg

##### Main outcome variables

vomiting

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151114025027N6**

Registration date: **2018-04-12, 1397/01/23**

Registration timing: **prospective**

Last update: **2018-04-12, 1397/01/23**

Update count: **0**

##### Registration date

2018-04-12, 1397/01/23

##### Registrant information

##### Name

Mohammadreza Maleki Varaki

##### Name of organization / entity

Ahvaz Judishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3374 3079

##### Email address

maleki-m@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-21, 1397/02/01

##### Expected recruitment end date

2018-05-20, 1397/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Study of the association of various ketamine doses with vomiting in children requiring sedation in the emergency department

## Public title

Ketamine associated vomiting in children require sedation

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients who require sedation for therapeutic or diagnostic process (reduction of fractures, CT scan, stitches, etc.) aged between 4 months to 13 years

### Exclusion criteria:

patients less than 3 months and more than 13 years patients who had vomiting before sedation patients who did not receive single-dose medication patients who suspected increased ICP asthma or previous adverse reaction to ketamine cardiovascular diseases or hypertension airway tract infections porphyria

## Age

From **4 months** old to **13 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **200**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random allocation sequence was determined from a computer-generated, random-number table, assigning patients in to two groups

## Blinding (investigator's opinion)

Not 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 Ahvaz Jundishapur University of Medical Sciences

##### Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khuzestan

## City

ahvaz

## Province

Khuzestan

## Postal code

61357-15794

## Approval date

2014-03-01, 1392/12/10

## Ethics committee reference number

ajums.REC.1392.346

## Health conditions studied

### 1

#### Description of health condition studied

Vomiting

#### ICD-10 code

R11.1

#### ICD-10 code description

Vomiting

## Primary outcomes

### 1

#### Description

vomiting

#### Timepoint

2 hours after injection

#### Method of measurement

Visual analog scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Patients in first group will receive ketamine via intravenous with dosage of 1 mg/kg

#### Category

Other

### 2

#### Description

Intervention group: Patients in Second group will receive ketamine via intravenous with dosage of 2 mg/kg

#### Category

Other

### 3

#### Description

Intervention group: Patients in Third group will receive ketamine via intramuscular with dosage of 3 mg/kg

#### Category

Other

#### 4

##### Description

Intervention group: Patients in Fourth group will receive ketamine via intramuscular with dosage of 5 mg/kg

##### Category

Other

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Ahvaz Golestan hospital

###### Full name of responsible person

Mohammadreza Maleki Varaki

###### Street address

Golestan hospital, Golestan road, Ahvaz, Khuzestan

###### City

ahvaz

###### Province

Khuzestan

###### Postal code

61357-15794

###### Phone

+98 61 3320 8342

###### Email

Maleki-m@ajums.ac

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Ahvaz University of Medical Sciences

###### Full name of responsible person

mohammad badavi

###### Street address

golestan

###### City

ahvaz

###### Province

Khuzestan

###### Postal code

61357-15794

###### Phone

+98 61 3320 8342

###### Email

Maleki-m@ajums.ac

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

###### Full name of responsible person

Mohammadreza Maleki Varaki

###### Position

Emergency medicine specialist

###### Latest degree

Specialist

###### Other areas of specialty/work

Emergency Medicine

###### Street address

Ahvaz Jundishapur University of Medical Sciences,  
Golestan road, Ahvaz, Khuzestan

###### City

ahvaz

###### Province

Khuzestan

###### Postal code

61357-15794

###### Phone

+98 61 3320 8342

###### Email

Maleki-m@ajums.ac

### Person responsible for scientific inquiries

##### Contact

###### Name of organization / entity

Ahvaz University of Medical Sciences

###### Full name of responsible person

Mohammadreza Maleki Varaki

###### Position

Emergency medicine specialist

###### Latest degree

Specialist

###### Other areas of specialty/work

Emergency Medicine

###### Street address

Ahvaz Jundishapur University of Medical Sciences,  
Golestan road, Ahvaz, Khuzestan

###### City

ahvaz

###### Province

Khuzestan

###### Postal code

61357-15794

###### Phone

+98 61 3320 8342

###### Email

Maleki-m@ajums.ac

## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Hassan Motamed

**Position**

Emergency medicine specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Ahvaz Jundishapur University of Medical Sciences,  
Golestan road, Ahvaz, Khuzestan

**City**

ahvaz

**Province**

Khuzestan

**Postal code**

61357-15794

**Phone**

+98 61 3320 8342

**Email**

hasan\_motamed@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable