

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

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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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammadreza Maleki Varaki

Position

Emergency medicine specialist

Latest degree

Specialist

Other areas of specialty/work

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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

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Phone

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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