

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### The effect of Ondansetron on the Incidence of Vomiting Associated With Ketamine Sedation in Children: A half-Blind Randomized, Controlled Trial

#### Protocol summary

##### Summary

ketamine is used as analgesic for performing procedures in emergency departments especially for children. Vomiting is one the most common adverse effects of ketamine injection. The goal of this study was to determine the effect of ondansetron on ketamine related vomiting in children. Children from 6months to 10years who will come to emergency department of Imam or Shariati hospital need procedural sedation analgesia, will randomly assigned to ketamine or ketamine plus ondansetron groups. Patients would exclude from the study, if they had any of exclusion criteria, such as allergy to ketamine or ondansetron, seizure, airway disease, head trauma, uncontrolled high blood pressure and vomiting before starting the process associated with other diseases, especially head trauma. Sample size determined at least 60 children in each groups, means totally 120 patients. The first group will receive 4 mg /kg ketamine (intramuscular) and the second group will receive the same dose of ketamine plus ondansetron (0.1 mg /kg, up to 2 mg) in the same syringe. Level of sedation, vital signs including pulse rate and SpO<sub>2</sub> and side effects especially nausea and vomiting will record during procedure, through recovery period and 4 hours after completion of the procedure.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201301189162N7**

Registration date: **2015-11-30, 1394/09/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-11-30, 1394/09/09

#### Registrant information

##### Name

Amir Nejati

##### Name of organization / entity

Tehran University of Medical Sciences, Imam Khomeini Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6119 2240

##### Email address

a-nejati@tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran University of Medical Sciences

#### Expected recruitment start date

2013-03-20, 1391/12/30

#### Expected recruitment end date

2014-03-20, 1392/12/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of Ondansetron on the Incidence of Vomiting Associated With Ketamine Sedation in Children: A half-Blind Randomized, Controlled Trial

#### Public title

ondansetron for reducing Ketamine related vomiting in children

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Exclusion criteria are: allergy to ketamine or ondansetron, seizure, air way disease, head trauma,

uncontrolled high blood pressure and vomiting associated with other diseases. children (6 months to 10 years) who will refer to emergency department of Imam or Shariati hospitals will be included.

#### Age

From **6 months** old to **10 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **120**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University Of Medical Science

##### Street address

Enghelab Square

##### City

Tehran

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

93/130/1113/د

## Health conditions studied

### 1

#### Description of health condition studied

nasea and vomiting

#### ICD-10 code

R11

#### ICD-10 code description

تهوع و استفراغ

## Primary outcomes

### 1

#### Description

vomitting

#### Timepoint

before procedure/during procedure/after discharge

#### Method of measurement

with quastion form

## Secondary outcomes

### 1

#### Description

Pulse Rate

#### Timepoint

Continuously during procedure time

#### Method of measurement

Pulse Oximetry

### 2

#### Description

Saturation of peripheral O2 (SpO2)

#### Timepoint

Continuously during procedure time

#### Method of measurement

Pulse Oximetry

### 3

#### Description

Other Side effects like: Seizure, Shivering,...

#### Timepoint

In Recovery Period

#### Method of measurement

Observation

## Intervention groups

### 1

#### Description

Control Group: Intramuscular injection of Ketamin 4 mg/kg

#### Category

Treatment - Drugs

### 2

#### Description

Intervention Group: Intramuscular injection of Ketamine 4 mg/kg + Ondansetron 0.1 mg/kg (max 2mg) in the same syringe

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shariati Hospital

**Full name of responsible person**

Hamideh Akbari

**Street address**

North Kargar Street

**City**

Tehran

**2****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Hamideh Akbari

**Street address**

Bagherkhan Street

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

University Research Manager

**Street address**

6th Floor, Central Building, Toos Ave, Keshavarz Blvd

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Emam Khomeini Hospital

**Full name of responsible person**

Hamideh Akbari

**Position**

residence of emergency medical science

**Other areas of specialty/work****Street address**

Enghelab Square, Gharib Street

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Emam Khomeini Hospital

**Full name of responsible person**

Amir Nejati

**Position**

emergency medicine professor

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

residence of emergency medicine

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**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*