

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 SpO₂ 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

nausea 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

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

Enghelab Square, Gharib Street

City

Tehran

Postal code**Phone**

+98 21 6643 7542

Fax**Email**

hamideh.akbari1079@gmail.com

Web page address**2****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Hamideh Akbari

Street address

Bagherkhan Street

City

Tehran

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

Emam Khomeini Hospital

Full name of responsible person

Amir Nejati

Position

emergency medicine professor

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

Enghelab square, Gharib hospital

City

Tehran

Postal code**Phone**

+98 21 6680 2838

Fax**Email**

nejati.am@gmail.com

Web page address**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

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

Emam Khomeini Hospital

Full name of responsible person

Hamideh Akbari

Position

residence of emergency medicine

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

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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