

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of sedation with intravenous and intramuscular Ketamin in children admitted to the emergency department: a Randomized Controlled Trial

Protocol summary

Summary

Object: Ketamine is an agent used broadly for pediatric procedural sedation and analgesia (PSA) in emergency departments. As choosing between intravenous (IV) and intramuscular (IM) injections is a matter of concern, we did comparison between two methods in terms of their efficacy and the rate of complications. **Design:** Sedation by Ketamine was performed according to standard guidelines. A nurse blinded to the intervention was presented at the side of the patients during the whole procedure and not only recorded the routine nursing observations and evaluations, but also any abnormal conditions until the patient recovered to his/her pre-procedure state. Venipuncture was performed for all patients to ensure from blindness of the nurses and physicians. **Setting:** This single-blind clinical trial was conducted within three months to 15 years old children, weighted more than 5 kilograms, and required PSA for short and painful emergency procedures, who presented to the emergency departments of Imam Reza and Hasheminejad Hospitals, Mashhad, Iran. Before any intervention, administered medication and its complications were thoroughly explained for their parents and written informed consent was given from them. **Participant:** 240 children were recruited using convenience sampling. They were randomly allocated in two groups of 120 patients by using block randomization method. Subjects with a history of allergy to Ketamine, severe cardiovascular diseases, thyroid disorders, head injury, central nervous system (CNS) disorders, glaucoma or acute globe injuries, history or evidence of psychosis, obstructive sleep apnea, active pulmonary diseases such as upper respiratory tract infection, tracheal stenosis or surgery, needed procedures associated with stimulation of posterior pharyngeal region, and those who were not willing to participate were excluded from the study. **Intervention:** The first group of patients received IV

Ketamine (1.5 mg/kg, Infusion by 100 milliliter normal saline; maximum dose 200 mg), and the second took as IM (4 mg/kg; maximum dose 200 mg). **Main outcome measures:** Indications for use, dose, side effects and efficacy of the medications as well as duration of the procedure and time to recovery were compared between two groups. At the end of the procedure, a specialist, who was blinded to the intervention, rated the efficacy of medicine in pain management and sedation as excellent (full sedation, immobility, and analgesia during the whole procedure), moderate (slight movements due to pain without interfering to procedure), and poor (movements associated with pain that interfered in the procedure).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071218454N1**

Registration date: **2014-12-30, 1393/10/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-30, 1393/10/09

Registrant information

Name

Mohammad Gharavi fard

Name of organization / entity

Mashhad University of Medical Sciences

Country

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Recruitment status**Recruitment complete****Funding source**

Vice chancellor for research of Mashhad University of Medical Sciences

Expected recruitment start date

2014-03-22, 1393/01/02

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sedation with intravenous and intramuscular Ketamin in children admitted to the emergency department: a Randomized Controlled Trial

Public title

A comparative clinical study of sedative effects of intravenous and intramuscular Ketamin in pediatric patients

Purpose

Treatment

Inclusion/Exclusion criteria

INCLUSION CRITERIA: Age three months to 15 years and had to undergo short and painful emergency procedures.

EXCLUSION CRITERIA: Subjects with a history of allergy to Ketamine; severe cardiovascular diseases; thyroid disorder; head injury; CNS disorders; glaucoma or acute globe injuries; and history or evidence of psychosis; obstructive sleep apnea; active pulmonary disease; tracheal stenosis or surgery; children needing procedures associated with stimulation of posterior pharyngeal region and not willing to participate

AgeFrom **3 months** old to **15 years** old**Gender**

Both

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **240****Randomization (investigator's opinion)**

N/A

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**

Mashhad University of Medical Sciences Ethics Committee

Street address

Vice chancellor for research Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah avenue, Mashhad, Iran.

City

Mashhad

Postal code**Approval date**

2013-05-18, 1392/02/28

Ethics committee reference number

104911

Health conditions studied**1****Description of health condition studied**

Anesthesia

ICD-10 code

F44.6

ICD-10 code description

Dissociative anesthesia

Primary outcomes**1****Description**

Sedation efficacy

Timepoint

During intervention

Method of measurement

Efficacy of medicine in pain management and sedation as excellent (full sedation, immobility, and analgesia during the whole procedure), moderate (slight movements due to pain without interfering to procedure), and poor (movements associated with pain that interfered in the procedure).

2**Description**

Respiratory Adverse Events

Timepoint

During intervention

Method of measurement

The need for supplemental oxygen, Ventilation with a bag-mask, Maneuver practices for maintaining the airway open, Insertion of airway, Respiratory stimulation, Respiratory depression with SpO2 <92% in any time of

administration of the drug until hospital discharge

3

Description

Procedure time

Timepoint

During intervention

Method of measurement

From the beginning of sedation till emergency discharge

Secondary outcomes

1

Description

Non respiratory adverse events

Timepoint

During intervention

Method of measurement

Dysphoria, Vomiting, Myoclonus, Nausea, Stiffness, Rash, Seizures, Restlessness

Intervention groups

1

Description

Patients in control group will receive Ketamine 1.5 ml / kg before procedures via intravenous infusion

Category

Treatment - Drugs

2

Description

In the intervention group the patients will receive intramuscular Ketamine at a dose of 4 ml / kg once before procedures

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza and Hasheminejad Hospital

Full name of responsible person

Behnaz Boroumand Rezazade

Street address

Emam Reza Hospital, Emam Reza square, Avicenna avenue, Mashhad, Iran.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah avenue, Mashhad.

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Behnaz Boroumand Rezazade

Position

Emergency Medicine Resident

Other areas of specialty/work

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Other areas of specialty/work

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Full name of responsible person

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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