Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Mohammad Gharavi fard
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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
Age
From **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 Univercity 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 begining of sedatiion 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 recieve Ketamine 1.5 ml / kg before procedures via intravenous infusion
Category
Treatment - Drugs

2

Description
In the intervention group the patients will receive intera muscular 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, Avicina 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
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Vice Chancellor for Research, Mashhad Uvivercity of Medical Sciences, Ghoreishi building, Daneshgah avenue, Mashhad.
City
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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 Borouman Rezazade
Position
Emergency Medicine Resident
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position

Assistant Professor of Emergency Medicine

Other areas of specialty/work

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Person responsible for updating data

Contact

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Other areas of specialty/work

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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