

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison Between Efficacy and Side Effects of Intravenous and Intramuscular Ketamine for Sedation of 1 to 6 Years Old Children

Protocol summary

Summary

Objectives: comparison and study of efficacy and side effects of intravenous and intramuscular ketamine for sedation of 1 to 6 years old children, setting and conduct: this Clinical Trial Study that done on 272 patients in case and control groups, we give intravenous ketamine for sedation to the control group and so the case group will receive intramuscular ketamine for sedation, Inclusion criteria: need for sedation to imaging; age below 6 years old Exclusion criteria: history of hypersensitivity to ketamine; evidences of abnormal brain; evidence of rise of intracranial pressure; history of apnea and respiratory disorders; history of severe traumatic brain injury; no sedation with standard dose; parental disagreement Observation: time to start sedation; sedation grade; blood pressure changes; vomiting; apnea; laryngospasm; in the case and control group Primary outcome measure: time to start sedation and grade of sedation comparison in each group will be done

General information

Acronym

Comparison Between Intravenous and Intramuscular Ketamine for Sedation of Children

IRCT registration information

IRCT registration number: **IRCT2016021826630N1**

Registration date: **2016-03-04, 1394/12/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-04, 1394/12/14

Registrant information

Name

Arash Forouzan

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Research Assistant of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Between Efficacy and Side Effects of Intravenous and Intramuscular Ketamine for Sedation of 1 to 6 Years Old Children

Public title

Comparison Between Efficacy and Side Effects of Intravenous and Intramuscular Ketamine for Sedation of 1 to 6 Years Old Children

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: need for sedation to imaging; age below 6 years old Exclusion criteria: history of hypersensitivity to ketamine; evidences of abnormal

brain; evidence of rise of intracranial pressure; history of apnea and respiratory disorders; history of severe traumatic brain injury; no sedation with standard dose; parental disagreement

Age

From **1 year** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **272**

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

Ethics Committee of Ahvaz University of Medical Sciences

Street address

Research Assistant, Next to central Building, Ahvaz Jundishapur University of Medical Sciences, University town, Ahvaz

City

Ahvaz

Postal code

Approval date

2015-11-30, 1394/09/09

Ethics committee reference number

ir.ajums.rec.1394.431

Health conditions studied

1

Description of health condition studied

Traumatic subdural haemorrhage

ICD-10 code

S06.5

ICD-10 code description

Traumatic subdural haemorrhage

2

Description of health condition studied

Epidural haemorrhage

ICD-10 code

S06.4

ICD-10 code description

Epidural haemorrhage

3

Description of health condition studied

Traumatic subarachnoid haemorrhage

ICD-10 code

S06.6

ICD-10 code description

Traumatic subarachnoid haemorrhage

Primary outcomes

1

Description

Time to start sedation

Timepoint

immediately after infusion of drug

Method of measurement

minutes

2

Description

Grade of sedation

Timepoint

1 minute after infusion, 5 minutes after infusion, 15 minutes after infusion

Method of measurement

Ramsay Sedation Scale

Secondary outcomes

1

Description

Vomiting

Timepoint

Up to one hour after infusion of drug

Method of measurement

Observation

2

Description

Apnea

Timepoint

Up to 15 minutes after infusion of drug

Method of measurement

Observation

3

Description

Seizure

Timepoint

Up to 15 minutes after infusion of drug

Method of measurement

Observation

Intervention groups**1****Description**

Control group: 1.5 mg per kilogram intravenous ketamine

Category

Other

2**Description**

Case group: 4 milligram per kilogram of body weight intramuscular ketamine

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Dr Arash Forouzan

Street address

Azadi Street

City

Ahvaz

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

Golestan Hospital

Full name of responsible person

Dr Arash Forouzan

Street address

Golestan Hospital

City

Ahvaz

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

Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Nader Saki

Street address

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

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 of Ahvaz Jundishapur 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**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Arash Forouzan

Position

Assistant Professor of Emergency Medicine

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

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

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Contact

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Full name of responsible person

Dr. Arash Forouzan

Position

Emergency Medicine Assistant Professor

Other areas of specialty/work

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Emergency Medicine department, Imam Khomeini
Hospital

City

Ahvaz

Postal code

Phone

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