Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

The effect of intravenous ketamine plus paracetamol versus intravenous paracetamol alone on postoperative pain, nausea and vomiting after pediatric adenotonsilectomy: a triple blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of intravenous ketamine plus paracetamol versus intravenous paracetamol alone on postoperative pain, nausea and vomiting after pediatric adenotonsilectomy. Design: A triple blinded randomized clinical trial. Setting and conduct: All eligible patients who are candidate for elective adenotonsilectomy and will refer to the Beasat Hospital during the study period will be enrolled in to the trial. Inclusion criteria: (a) 3 to 12 years old; (b) candidate for elective adenotonsilectomy; having one or two criteria based on Physical Status Classification American Society of Anesthesiologists (ASA) Exclusion criteria: (a) history of psychiatric disease; (b) using analgesic within 24 hours before surgery; (c) sensitivity to ketamine or acetaminophen; (d) using cautery for hemostasis. Intervention: Intravenous ketamine 0.25 mg/kg (2 ml) single dose plus intravenous acetaminophen 15 mg/kg single dose, 15 min before the end of surgery and every 6 hours until 24 hours after surgery. Control: Intravenous normal saline 2 ml single dose plus intravenous acetaminophen 15 mg/kg single dose, 15 min before the end of surgery and every 6 hours until 24 hours after surgery. Primary outcome: (a) Pain severity at 0.5, 6, 12, and 12 hours after surgery based on the CHEOPS Pain Score; (b) Number of nausea and vomiting at 0.5, 6, 12, and 12 hours after surgery based on clinical observation. Secondary outcome: The duration of time per min after surgery to using the first narcotic based on medical record.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402179014N25**

Registration date: **2014-05-26, 1393/03/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-26, 1393/03/05

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intravenous ketamine plus paracetamol

versus intravenous paracetamol alone on postoperative pain, nausea and vomiting after pediatric adenotonsilectomy: a triple blinded randomized clinical trial

Public title
The effect of intravenous ketamine plus paracetamol versus intravenous paracetamol alone on postoperative pain, nausea and vomiting after pediatric adenotonsilectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: (a) 3 to 12 years old; (b) candidate for elective adenotonsilectomy; having one or two criteria based on Physical Status Classification American Society of Anesthesiologists (ASA) Exclusion criteria: (a) history of psychiatric disease; (b) using analgesic within 24 hours before surgery; (c) sensitivity to ketamine or acetaminophen; (d) using cautery for hemostasis.
Age
From **3 years** old to **12 years** old
Gender
Male

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **98**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization: Using balance blocks randomization with block of four. Blinding: The drugs are prescribed during surgery hence the patients will not aware of the type of medications. Furthermore, the anesthesiologist who will assess the effect of the intervention will be aware of the coding of the intervention and control groups. In addition, the analyzer will not aware of the coding either. Therefore, the trial will be run triple blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Approval date
2014-05-17, 1393/02/27
Ethics committee reference number
P/16/35/9/709

Health conditions studied

1

Description of health condition studied
Pain in throat
ICD-10 code
R07.0
ICD-10 code description
Pain in throat

2

Description of health condition studied
Nausea and vomiting
ICD-10 code
R11
ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Pain severity
Timepoint
at 0.5, 6, 12, and 12 hours after surgery
Method of measurement
based on the CHEOPS Pain Score

2

Description
Number of nausea and vomiting
Timepoint
at 0.5, 6, 12, and 12 hours after surgery
Method of measurement
based on clinical observation

Secondary outcomes

1

Description
The duration of time to use the first narcotic
Timepoint
per min after surgery
Method of measurement

based on medical record

Intervention groups

1

Description
Intravenous ketamine 0.25 mg/kg (2 ml) single dose plus intravenous acetaminophen 15 mg/kg single dose, 15 min before the end of surgery and every 6 hours until 24 hours after surgery.
Category
Treatment - Drugs

2

Description
Intravenous normal saline 2 ml single dose plus intravenous acetaminophen 15 mg/kg single dose, 15 min before the end of surgery and every 6 hours until 24 hours after surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Beasat Hospital
Full name of responsible person
Dr Hossein Kimiaei
Street address
Beasat Hospital, Shahed Square
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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Hamadan
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 the Technology, Hamadan 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
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Full name of responsible person
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Web page address

Person responsible for updating data

Contact

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