Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparison Of Nebulized Ketamine With Intravenous Paracetamol Versus Paracetamol Alone For Post-Operative Analgesia In Paediatric Day Care Anesthesia

Protocol summary

Study aim

Our study aims to study the analgesic efficacy of the nebulized form ketamine with intravenous paracetamol versus paracetamol alone for post-operative analgesia in pediatric cases undergoing general anesthesia for elective tonsillectomy as a day care procedure.

Design

Prospective Study, parallel group, double blind study, non probability consecutive sampling

Settings and conduct

a double-blind method was used to prevent bias. Participants in group K received intravenous paracetamol 10 mg/kg with nebulized ketamine 2 mg/kg diluted in 5 ml given over 5 minutes 15 minutes before induction whereas group P received intravenous paracetamol 15 mg/kg with nebulization with 5 ml normal saline as placebo 15 minutes before the procedure. The anesthetist preparing the solutions was given sealed non-descript bottles with the nebulizing preparations and the trainee in the operating room did not know of the drug in the nebulizer while also unaware of the study protocol.

Participants/Inclusion and exclusion criteria

Inclusion criteria included all ASA-I and II male and female pediatric patients aged 7-12 years coming to the pre-anesthesia clinic for elective tonsillectomy as a day care procedure. Exclusion criteria included patients with any co-morbidity requiring admission, history of upper or lower respiratory tract infection in the last 2 weeks, major cardiovascular abnormalities, un co-operative patients and patients unwilling to be included in the study.

Intervention groups

Patients were divided into two groups K and P with group P to receive intravenous paracetamol 10 mg/kg pre-operatively while group K to receive pre-operative intravenous paracetamol at 10 mg/kg along with nebulized ketamine at 2 mg/kg 15 minutes before induction.

Main outcome variables

Post-operative median pain scores were calculated in the recovery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230809059095N1**
Registration date: **2023-09-08, 1402/06/17**
Registration timing: **retrospective**

Last update: **2023-09-08, 1402/06/17**
Update count: **0**

Registration date

2023-09-08, 1402/06/17

Registrant information

Name

Hassan Minhas

Name of organization / entity

Combined Military Hospital, Rawalpindi, Pakistan

Country

Pakistan

Phone

+92 345 5264734

Email address

h.hassan.nasir@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-01, 1400/10/11

Expected recruitment end date

2022-07-31, 1401/05/09

Actual recruitment start date
2022-01-01, 1400/10/11

Actual recruitment end date
2022-07-31, 1401/05/09

Trial completion date
2022-07-31, 1401/05/09

Scientific title
Comparison Of Nebulized Ketamine With Intravenous Paracetamol Versus Paracetamol Alone For Post-Operative Analgesia In Paediatric Day Care Anesthesia

Public title
Efficacy of Nebulized Ketamine for Post-Operative Analgesia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
ASA 1 and 2 patients for Elective Tonsillectomy day care procedure Ages 7 - 12 years

Exclusion criteria:
comorbidities requiring admission Respiratory Tract Infections in preceding 2 weeks Uncooperative unwilling patients

Age
From **7 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **181**
Actual sample size reached: **190**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients were received in the recovery room 1 hour before the procedure and after informed written consent and details of being included in the study, a double-blind method was used to prevent bias. Participants in group K received intravenous paracetamol 10 mg/kg with nebulized ketamine 2 mg/kg diluted in 5 ml given over 5 minutes 15 minutes before induction whereas group P received intravenous paracetamol 15 mg/kg with nebulization with 5 ml normal saline as placebo 15 minutes before the procedure. The anesthetist preparing the solutions was given sealed non-descript bottles with the nebulizing preparations and the trainee in the operating room did not know of the drug in the nebulizer while also unaware of the study protocol.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Combined Military Hospital, Rawalpindi, Pakistan

Street address
CMH Road

City
Rawalpindi

Postal code
46000

Approval date
2021-12-25, 1400/10/04

Ethics committee reference number
261/2021

Health conditions studied

1

Description of health condition studied
Post-Operative Analgesia

ICD-10 code
J02.9

ICD-10 code description
Acute pharyngitis, unspecified

Primary outcomes

1

Description
Post Operative Pain

Timepoint
15, 30, 120 minutes

Method of measurement
Wong Baker faces scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group - ketamine, Participants in this group

received intravenous paracetamol 10 mg/kg with nebulized ketamine 2 mg/kg diluted in 5 ml given over 5 minutes 15 minutes before induction

Category

Treatment - Drugs

2

Description

Control group - placebo, This group received intravenous paracetamol 15 mg/kg with nebulization with 5 ml normal saline as placebo 15 minutes before the procedure

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Combined Military Hospital

Full name of responsible person

Hassan Nasir Minhas

Street address

CMH Road

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Phone

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Email

h.hassan.nasir@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Armed Forces Post Graduate Medical Institute

Full name of responsible person

Hassan Nasir Minhas

Street address

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Email

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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

Armed Forces Post Graduate Medical Institute

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Armed Forces Post Graduate Medical Institute

Full name of responsible person

HassanNasir Minhas

Position

Registrar

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Armed Forces Post Graduate Medical Institute

Full name of responsible person

HassanNasir Minhas

Position

Registrar

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity
Armed Forces Post Graduate Medical Institute

Full name of responsible person
HassanNasir Minhas

Position
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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available