Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Role of Dexmedetomidine in reduction of Post-Operative Emergence Delirium in children undergoing Adenotonsillectomy

Protocol summary

Study aim

Our study aims to use dexmedetomidine in reduction of emergence delirium in children undergoing elective adenotonsillectomy after general anesthesia.

Design

This quasi experimental study was carried out at the Department of Anesthesiology, Combined Military Hospital from Jun-Dec 2023. A total of 90 patients (WHO minimum sample size 28) were included in the study keeping the confidence interval at 95%, power of test at 80%, with the proportion of children experiencing emergence delirium with per-operative dexmedetomidine infusion compared to placebo at 26% versus 60.8%10.

Settings and conduct

Double blinding where study group, resident and accessor were unaware.

Participants/Inclusion and exclusion criteria

Inclusion criteria included all ASA-I and II pediatric patients aged 6-12 years of age presenting in the pre-anesthesia clinic requiring general anesthesia fitness for elective adenotonsillectomy. Exclusion criteria included patients with congenital anomalies, history if ICU admission in the last 3 months, advanced cardiac or respiratory disease, patients on anti-psychotics or mood stabilizers, allergic to dexmedetomidine and patients or their parents unwilling to be included in the study.

Intervention groups

Patients were divided into two groups as per the inclusion criteria and sampling technique specified. After being divided into two groups, Group D (n=45) to receive per-operative intravenous infusion of dexmedetomidine at 0.3 mcg/kg dilutes in 50 ml of normal saline over 5 minutes and Group P (n=45) to receive the placebo dosing of 50 ml normal saline over 5 minutes.

Main outcome variables

Primary variables studies were the total incidence of emergence delirium between both groups, median PAED (pediatric assessment emergence delirium) score .

Secondary variables measured were mean time to discharge and total dose of analgesia required post-operatively.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240402061403N1**
Registration date: **2024-05-02, 1403/02/13**
Registration timing: **retrospective**

Last update: **2024-05-02, 1403/02/13**
Update count: **0**

Registration date

2024-05-02, 1403/02/13

Registrant information

Name
Dain Bin Khalid

Name of organization / entity
National University of Medical Sciences

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Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2023-09-10, 1402/06/19

Actual recruitment start date

2023-06-14, 1402/03/24

Actual recruitment end date
2023-09-21, 1402/06/30
Trial completion date
2023-12-28, 1402/10/07

Scientific title
Role of Dexmedetomidine in reduction of Post-Operative Emergence Delirium in children undergoing Adenotonsillectomy

Public title
Reduction of Emergence Delirium In Children Undergoing Adenotonsillectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
ASA-I and II pediatric patients aged 6-12 years Patients undergoing adenotonsillectomy under General Anaesthesia
Exclusion criteria:
Patients with congenital anomalies, History of ICU admission in last 3 months Cardiac or respiratory disease Patients on anti psychotics and mood stabilizers Allergic to dexmedetomidine Patients unwilling to be included in the study
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Actual sample size reached: **90**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
The resident on duty received pre-made burettes marked X or Y in one of the two groups without knowledge of the drug or dose titration and unaware of the study protocol. To prevent bias, patients were also not made aware of which group was to receive the drug and which was to receive placebo. The drugs were prepared by an independent consultant in the recovery room and result complied by the resident were handed over to a third consultant involved in data analysis.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National University of Medical Sciences
Street address
Pak Emirates Military Hospital Rawalpindi
City
Rawalpindi
Postal code
46000
Approval date
2023-06-06, 1402/03/16
Ethics committee reference number
529

Health conditions studied

1

Description of health condition studied
Emergence Delirium in children after undergoing Adenotonsillectomy in General Anesthesia
ICD-10 code
F05
ICD-10 code description
Delirium due to known physiological condition

Primary outcomes

1

Description
Incidence of emergence delirium between the two groups who were administered dexmedetomidine and placebo.
Timepoint
Pre-Operatively, Post-Operatively at 30 minutes and 1 hour
Method of measurement
PAED (pediatric assessment emergence delirium) score and Watcha delirium score

Secondary outcomes

1

Description
MEAN TOTAL DOSE OF ANALGESIA USED AND MEAN TOTAL RECOVERY TIME (TILL DISCHARGE)
Timepoint
(RECOVERY TILL DISCHARGE)
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group: Group D (n=45) received per-operative intravenous infusion of dexmedetomidine at 0.3 mcg/kg dilutes in 50 ml of normal saline over 5 minutes
Category
Treatment - Drugs

2

Description
Control group: Group P (n=45) received the placebo dosing of 50 ml normal saline over 5 minutes.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Combined Military Hospital Rawalpindi
Full name of responsible person
Dr Dain Bin Khalid
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Sponsors / Funding sources

1

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Web page address
Grant name
NUMS Research Funding Program
Grant code / Reference number
1542
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National University of Medical Sciences
Proportion provided by this source
70
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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Role of Dexmedetomidine in reduction of Post-Operative Emergence Delirium in children undergoing Adenotonsillectomy
When the data will become available and for how long
February 2025 to 1 year after publication
To whom data/document is available
All the residents and consultants working in Anesthesiology and Otorhinolaryngology
Under which criteria data/document could be used
documents can be used for similar researches for references and data and 1st two authors can be contacted via emails for access
From where data/document is obtainable
www.pafmj.org
What processes are involved for a request to access data/document
any of the authors including me can be contacted on email for data access
Comments