

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Country

Pakistan

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+92 324 4129326

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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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AMC Officers Mess Convoy Road Rawalpindi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Contact

Name of organization / entity

National University of Medical Sciences

Full name of responsible person

Hafiz Arslan Arshad

Position

Resident Anaesthesiology

Latest degree

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Person responsible for updating data

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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