

# 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%<sup>10</sup>.

##### 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 of 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

##### Phone

+92 324 4129326

##### Email address

dainbinkhalid7073@gmail.com

##### 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

#### Street address

AMC Officers Mess Convoy Road Rawalpindi

#### City

Rawalpindi

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46000

#### Phone

+92 324 4129326

#### Email

dainbinkhalid7073@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

National University of Medical Sciences

#### Full name of responsible person

Dr Tufail Ahmed

#### Street address

National University of Medical Sciences The Mall  
Rawalpindi Pakistan

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Rawalpindi

#### Postal code

49000

#### Phone

+92 322 8487073

#### Email

aqeel.yunus@numspak.edu.pk

#### 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

Medical doctor

#### Other areas of specialty/work

Anesthesiology

#### Street address

AMC Officers Mess Rawalpindi

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

National University of Medical Sciences

#### Full name of responsible person

Munim Ilyas

#### Position

Resident Anaesthesiology

#### Latest degree

Medical doctor

#### Other areas of specialty/work

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**Person responsible for updating data****Contact****Name of organization / entity**

National University of Medical Sciences

**Full name of responsible person**

Shujaat Hussain

**Position**

Resident Anaesthesiology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Phone**

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**Email**

shujaat169@yahoo.com

**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**