

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparison of Efficacy of Intranasal versus Intravenous Dexmedetomidine for Procedural Sedation in Pediatric Patients Undergoing Magnetic Resonance Imaging

Protocol summary

Study aim

To compare the outcomes of intranasal versus intravenous dexmedetomidine for procedural sedation in pediatric patients undergoing MRI.

Design

Non Randomized Control Trial

Settings and conduct

Setting: Department of Radiology and Imaging Conduct: Data will be collected prospectively after approval of the synopsis, from eligible children aged 1 month–12 years requiring MRI under sedation, following pre-anesthesia assessment and written informed consent. Participants will be consecutively allocated by alternate assignment into Group A (intranasal dexmedetomidine, n=63) and Group B (intravenous dexmedetomidine, n=63). Standard monitoring will be applied, and sedation depth will be assessed every 5 minutes using the University of Michigan Sedation Scale (UMSS), with MRI initiated once UMSS ≥ 2 is achieved. Sedation onset time, duration, physiological parameters, rescue sedation requirements, and adverse events will be recorded. Failure to achieve adequate sedation within 20 minutes or significant movement during MRI requiring rescue sedation will be considered primary sedation failure

Participants/Inclusion and exclusion criteria

INCLUSION CRITERIA: Children aged 1 month to 12 years scheduled for elective MRI. American Society of Anesthesiologists (ASA) physical status I and II.
EXCLUSION CRITERIA: Known allergy to dexmedetomidine. Contraindications to dexmedetomidine (cardiac failure, cardiac arrhythmias, long QT syndrome, baseline bradycardia or hypotension, use of beta-blockers or digoxin, uncontrolled arterial hypertension, or recent stroke/intracranial bleeding). For the intranasal group only: children with URTI or nasal blockage within the preceding two weeks, as this alters mucosal drug absorption.

Intervention groups

Two Groups. Group A for Intranasal Rout Group B for Intravenous rout

Main outcome variables

Onset time Duration Recovery time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260824070775N1**

Registration date: **2026-09-02, 1405/06/11**

Registration timing: **prospective**

Last update: **2026-09-02, 1405/06/11**

Update count: **0**

Registration date

2026-09-02, 1405/06/11

Registrant information

Name

Hassaan Ghani

Name of organization / entity

Combined military Hospital

Country

Pakistan

Phone

+92 317 1669946

Email address

hassaan.ghani.gb@gmail.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-01, 1405/08/10

Expected recruitment end date

2027-04-30, 1406/02/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Efficacy of Intranasal versus Intravenous Dexmedetomidine for Procedural Sedation in Pediatric Patients Undergoing Magnetic Resonance Imaging

Public title
Comparison of Efficacy of Intranasal versus Intravenous Dexmedetomidine for Procedural Sedation in Pediatric Patients Undergoing Magnetic Resonance Imaging

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 1 month to 12 years scheduled for elective MRI. American Society of Anesthesiologists (ASA) physical status I and II
Exclusion criteria:
Known allergy or previous anaphylaxis to dexmedetomidine. Contraindications to dexmedetomidine (cardiac failure, cardiac arrhythmias, long QT syndrome, baseline bradycardia or hypotension, use of beta-blockers or digoxin, uncontrolled arterial hypertension, or recent stroke/intracranial bleeding). For the intranasal group only: children with an upper respiratory tract infection or nasal blockage within the preceding two weeks, as this alters mucosal drug absorption

Age
From **1 month** old to **12 years** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee Pak Emirates Military Hospital
Rawalpindi

Street address

Mall Road Rawalpindi

City

Rawalpindi

Postal code

46000

Approval date

2026-01-07, 1404/10/17

Ethics committee reference number

A/28/04/26

Health conditions studied

1

Description of health condition studied

Procedural Sedation. Procedural anxiety

ICD-10 code

F13.90

ICD-10 code description

Sedative, hypnotic, or anxiolytic use, unspecified, uncomplicated

Primary outcomes

1

Description

Onset of Sedation

Timepoint

Baseline (pre-sedation), every 5 minutes during the drug onset period

Method of measurement

The University of Michigan Sedation Scale (UMSS)

2

Description

Duration of Sedation

Timepoint

every 5 minutes after the drug onset period till completion of the MRI scan

Method of measurement

The University of Michigan Sedation Scale (UMSS)

3

Description

Recovery Time

Timepoint

every 5 minutes in the post-sedation recovery unit until the patient returns to baseline status (UMSS score 0)

Method of measurement

The University of Michigan Sedation Scale (UMSS)

Secondary outcomes

1

Description

Incidence of Treatment-Related Adverse Events like Bradycardia and hypotension

Timepoint

Baseline (pre-sedation), every 5 minutes during the MRI scan, and every 15 minutes in the recovery unit until discharge

Method of measurement

Tracking the frequency of specific clinical events, including bradycardia (heart rate lower than age-adjusted normal limits), hypotension (blood pressure lower than age-adjusted normal limits)

Intervention groups

1

Description

Intranasal dexmedetomidine group: Dexmedetomidine at a dose of 2–3 µg/kg will be administered as nasal drops divided equally between both nostrils approximately 30–45 minutes before imaging. The child will be kept in a supine position for 1–2 minutes to optimize mucosal absorption, and the dose may be repeated up to a maximum of 200 µg if necessary.

Category

Treatment - Drugs

2

Description

Intravenous dexmedetomidine group: Venous access will be secured by phlebotomist (more than 5 years of experience) and dexmedetomidine will be administered as a loading dose of 0.5–2 µg/kg over 10 minutes, followed by a maintenance infusion of 0.5–1.5 µg/kg/hour, adjusted according to the required level of sedation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pak Emirates Military Hospital Rawalpindi

Full name of responsible person

Hassaan Ghani

Street address

House 11 Street 3 New Harley Street Rawalpindi

City

Rawalpindi

Postal code

408000

Phone

+92 317 1669946

Email

hassaan.ghani.gb@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pak Emirates Military Hospital Rawalpindi

Full name of responsible person

Hassaan Ghani

Street address

House 11 Street 3 New Harley Street Rawalpindi

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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

Pak Emirates Military Hospital Rawalpindi

Proportion provided by this source

100

Public or private sector

Public

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

Pak Emirates Military Hospital Rawalpindi

Full name of responsible person

Hassaan Ghani

Position

Post Graduate Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

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City

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Postal code

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Pak Emirates Military Hospital Rawalpindi
Full name of responsible person
Hassaan Ghani
Position
Post Graduate Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Pak Emirates Military Hospital Rawalpindi
Full name of responsible person
Hassaan Ghani
Position

Post Graduate Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Individual participant data will not be shared outside the primary research team due to institutional policy and patient privacy restrictions governing pediatric medical records. Aggregate results will be made fully available through publication

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available