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
City
Rawalpindi
Postal code
408000
Phone
+92 317 1669946
Email
hassaan.ghani.gb@gmail.com
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
House 11 Street 3 New Harley Street Rawalpindi
City
Rawalpindi
Province
Punjab
Postal code
408000

Phone
+92 317 1669946
Email
hassaan.ghani.gb@gmail.com

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
Anesthesiology
Street address
House 11 Street 3 New Harley Street Rawalpindi
City
Rawalpindi
Province
Punjab
Postal code
408000
Phone
+92 317 1669946
Email
hassaan.ghani.gb@gmail.com

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
Anesthesiology
Street address
House 11 Street 3 New Harley Street Rawalpindi
City
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Province
Punjab
Postal code
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Phone
+92 317 1669946
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hassaan.ghani.gb@gmail.com

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