Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Dexmedetomidine versus propofol for maintenance of anesthesia after sevoflurane induction in children undergoing MRI.

Protocol summary

Study aim
To compare clinical parameters and post-operative recovery when using dexmedetomidine versus propofol after induction with sevoflurane in children undergoing elective diagnostic MRI (magnetic resonance imaging).

Design
Randomized controlled trial

Settings and conduct
This randomized controlled trial was carried out at the Department of Anesthesia, Combined Military Hospital Rawalpindi from Jan 2023-Jun 2023

Participants/Inclusion and exclusion criteria
Inclusion criteria: included all children aged 1-12 years of age presenting to the pre-anesthesia clinic for diagnostic MRI. Exclusion criteria: included patients <1 and >18 years, children with congenital heart disease or other congenital anomalies of major organs, children with known allergy to propofol or dexmedetomidine, children with major cardiac or respiratory disease, history of general anesthesia in the last 8 weeks, children with respiratory tract infections and children requiring intubation during the procedure for any indication required.

Intervention groups
Inhalational induction with Sevoflurane 1.0 MAC (minimum alveolar concentration) was carried out and weight and age-appropriate i-gel (Laryngeal mask airway) was inserted to secure the airway. Maintenance of anesthesia was then carried out with IV Propofol and IV Dexmedetomidine in respective groups. Sevoflurane was then shut off and maintenance doses of both drugs were started. Patients in Group P (IV Propofol) received a maintenance infusion of 100 mcg/kg/min whereas patients in Group D (IV Dexmedetomidine) received a dose of 1 mcg/kg/hour titrated in an infusion pump till the time of completion of the procedure.

Main outcome variables
heart rate, mean arterial pressure, and respiratory rate recorded every 5 minutes during the maintenance of anesthesia till the end of the procedure.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231124060161N1**
Registration date: **2024-04-29, 1403/02/10**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-29, 1403/02/10**
Update count: **0**

Registration date
2024-04-29, 1403/02/10

Registrant information

Name
Saddam Hussain

Name of organization / entity
Combined military hospital rawalpindi

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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-01, 1401/10/11

Expected recruitment end date
2024-06-01, 1403/03/12

Actual recruitment start date
2023-01-01, 1401/10/11

Actual recruitment end date
2024-06-01, 1403/03/12

Trial completion date
2024-06-01, 1403/03/12

Scientific title
Dexmedetomidine versus propofol for maintenance of anesthesia after sevoflurane induction in children undergoing MRI.

Public title
Dexmedetomidine versus propofol for maintenance of anesthesia after sevoflurane induction in children undergoing MRI.

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
all children aged 1-12 years of age presenting to the pre-anesthesia clinic for diagnostic MRI.
Exclusion criteria:
patients <1 and >18 years. children with congenital heart disease or other congenital anomalies of major organs. children with known allergy to propofol or dexmedetomidine. children with major cardiac or respiratory disease. history of general anesthesia in the last 8 weeks. children with respiratory tract infections and children requiring intubation during the procedure for any indication required..

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **140**
Actual sample size reached: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
. The patients were randomized into two groups of 70 patients each. After confirming nil per oral status in the recovery room of the MRI suite on the day of the procedure, an informed written consent was taken from the next of kin and they were explained about the parameters of the study protocol. Before going into the MRI suite, age, weight, and gender were recorded by a resident anesthetist unaware of the study protocol. Basic vital monitoring including blood pressure, heart rate, saturation, and electrocardiogram was attached. Pre-oxygenation was done with a good seal and appropriately sized facemask and continued till end-tidal O2 levels on the anesthesia machine were >90%. Inhalational induction with Sevoflurane 1.0 MAC (minimum alveolar concentration) was then carried out and weight and age-appropriate i-gel (Laryngeal mask airway) was inserted to secure the airway. Maintenance of anesthesia was then carried out with IV Propofol and IV Dexmedetomidine in respective groups. Sevoflurane was then shut off and maintenance doses of both drugs were started. Patients in Group P (IV Propofol) received a maintenance infusion of 100 mcg/kg/min whereas patients in Group D (IV Dexmedetomidine) received a dose of 1 mcg/kg/hour titrated in an infusion pump till the time of completion of the procedure. The infusion pumps were marked as X and Y and prepared by the consultant on duty to ensure blinding and parameters studies were recorded on a proforma given to the resident anesthetist on duty in the suite unaware of the study protocol or the drug used. Per-operative bradycardia (HR<80 and <60 according to respective age) was managed with IV atropine 0.02 mg/kg and hypotension (MAP <60) was managed with IV phenylephrine 10 mcg bolus12.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The patients were randomized into two groups of 70 patients each. After confirming nil per oral status in the recovery room of the MRI suite on the day of the procedure, an informed written consent was taken from the next of kin and they were explained about the parameters of the study protocol.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee Review board
Street address
CMH road rawalpindi
City
Rawalpindi
Postal code
46000

Approval date
2023-08-01, 1402/05/10

Ethics committee reference number
542

Health conditions studied

1

Description of health condition studied
post-operative recovery in children undergoing elective diagnostic MRI (magnetic resonance imaging).

ICD-10 code
Y48.4

ICD-10 code description
Anaesthetic, unspecified

Primary outcomes

1

Description
heart rate
Timepoint
Before intervention and after 5 minutes after.
Method of measurement
Cardiac monitor, pulse oximetry, ECG

2

Description
mean arterial pressure
Timepoint
Before intervention and after 5 minutes after.
Method of measurement
Cardiac monitor, sphygmomanometer

3

Description
respiratory rate
Timepoint
Before intervention and after 5 minutes after.
Method of measurement
Ventilator parameter

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Inhalational induction with Sevoflurane 1.0 MAC (minimum alveolar concentration) was then carried out and weight and age-appropriate i-gel (Laryngeal mask airway) were inserted to secure the airway. Maintenance of anesthesia was then carried out with IV Propofol and IV Dexmedetomidine in respective groups.
Category
Treatment - Drugs

2

Description
Intervention group: . Patients in Group P (IV Propofol) received a maintenance infusion of 100 mcg/kg/min.
Category
Treatment - Drugs

3

Description
Intervention group: whereas patients in Group D (IV Dexmedetomidine) received a dose of 1 mcg/kg/hour titrated in an infusion pump till the time of completion of the procedure.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
CMH Rawalpindi
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
Combined military hospital Rawalpindi Pakistan
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
CMH Rawalpindi
Proportion provided by this source
100
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
CMH Rawalpindi

Full name of responsible person
Saddam Hussain

Position
Registrar Anaesthesiology

Latest degree
Bachelor

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available