

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Country

Pakistan

Phone

+92 344 9017071

Email address

saddam13315@gmail.com

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

Saddam Hussain

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Email

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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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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

saddam13315@gmail.com

Contact

Name of organization / entity
CMH Rawalpindi
Full name of responsible person
Saddam Hussain
Position
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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