

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The Impact of ADRA2A and CYP2A6 Gene Polymorphism on sedative and analgesic effect of Dexmedetomidine

Protocol summary

Study aim

Aim: To explore the possible association of CYP2A6 and ADRA2A genetic variants altering in dexmedetomidine response in Pakistani patients. Objectives: 1. To determine the frequency of genes polymorphism in CYP2A6 and ADRA2A in Pakistani patients. 2. To correlate ADRA2A gene polymorphisms with clinical effects of dexmedetomidine 3. To determine the association of CYP2A6 polymorphism to serum concentration of dexmedetomidine.

Design

Interventional, single blinded parallel longitudinal study

Settings and conduct

The study will be conducted at Pakistan Ordinance Factories (POFs) Hospital and Wah Medical College(WMC), Wah Cantt, in collaboration with Islamic International Medical College (IIMC) Rawalpindi Pakistan,

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pakistani individuals between of age 06-60 years undergoing elective surgeries selected according to American Society of Anesthesiology classification I-II (Healthy person, Mild systemic disease)
Exclusion criteria: Patients with • Hypertension & Diabetes • Pulmonary diseases • Arrhythmias • Compromised renal and hepatic functions • Cognitive impairment, neurological disease • Pre-operative morphine consumption, or on antidepressant, on drug abuse • Non- Pakistani origin • Patients not giving consent • Females not pregnant

Intervention groups

Intervention Group will be administered 1µg/kg dexmedetomidine hydrochloride intravenously over 10 min as a bolus just before the induction in addition to the standard anaesthesia protocol, followed by maintenance dose of 0.5 µg/kg/hr. till the end of surgery.

Main outcome variables

Sedation, Analgesia, Genotyping and Polymorphism in Receptor and enzyme determining the pharmacodynamic and pharmacokinetic of

dexmedetomidine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230824059251N1**

Registration date: **2023-09-01, 1402/06/10**

Registration timing: **prospective**

Last update: **2023-09-01, 1402/06/10**

Update count: **0**

Registration date

2023-09-01, 1402/06/10

Registrant information

Name

Khalida Ajmal

Name of organization / entity

Wah Medical College--A project of POF Trust

Country

Pakistan

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+92 51 9094000

Email address

mrskhalida57@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-10, 1402/06/19

Expected recruitment end date

2023-12-30, 1402/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Impact of ADRA2A and CYP2A6 Gene Polymorphism on sedative and analgesic effect of Dexmedetomidine

Public title

Dexmedetomidine as adjuvant to anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

ASA I & II Pakistani origin

Exclusion criteria:

No co-morbidity Non pregnant females

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

- Participant

Sample size

Target sample size: **300**

More than 1 sample in each individual

Number of samples in each individual: **3**

blood samples taken at 0, 1/2 hrs and 2 hrs time interval

Randomization (investigator's opinion)

Randomized

Randomization description

The patients fulfilling the inclusion criteria, will be randomized into two groups by computer generated random numbers (Simple randomization) by assigning participants in control group with odd numbers and intervention group with even number. Intervention group will be administered 1 µg/kg dexmedetomidine hydrochloride diluted in 20ml normal saline intravenously over 10 min as a bolus just before the induction in addition to the standard anaesthesia protocol, followed by maintenance dose of 0.5 µg/kg/hr in another 20 ml of saline till the end of surgery. The control group will receive 20ml intravenous infusion of normal saline 0.9 % over 10 minutes followed by continuous infusion of 12.5 ml of normal saline till the end of surgery in addition to anesthetic agents decided. Pre-operative variable like demographic data, hemodynamics profile, then at three point interval blood sampling for drug levels, anti-inflammatory markers and genotyping and levels of analgesia and sedation will be assessed as described in next section.

Blinding (investigator's opinion)

Single blinded

Blinding description

All participants were not given information about the investigational drug. Half of the participants were included in control group and the other half as interventional study group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Review Committee (IRC) Islamic International Medical College

Street address

276, Peshawer Road

City

Rawalpindi

Postal code

46000

Approval date

2023-01-06, 1401/10/16

Ethics committee reference number

Ripah/IRC/23/101

Health conditions studied**1****Description of health condition studied**

Intraoperative sedation and analgesia

ICD-10 code

U00-U85

ICD-10 code description

The drug under study will be given as adjuvant to anesthesia to produce sedation and analgesia and reduce the dose of anesthetic agents, analgesic and drugs for nausea & vomiting.

Primary outcomes**1****Description**

Intraoperative sedation and analgesia

Timepoint

before intervention and at 1/2 an hour interval and at 2hrs interval

Method of measurement

Ramsay Sedation scale, Visual analogue scale and polymorphism in genes

2**Description**

Genotyping and Polymorphism in Receptor gene and in enzyme gene

Timepoint

Polymorphism can be studied both in control and study group in blood sample of 2hrs interval

Method of measurement

Drug concentration will be measured at 30 min and at 2hrs interval in both groups

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: intervention Group will be administered 1µg/kg dexmedetomidine hydrochloride intravenously over 10 min as a bolus just before the induction in addition to the standard anaesthesia protocol, followed by maintenance dose of 0.5 µg/kg/hr. till the end of surgery.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Pakistan Ordinance Factories Hospital , patients attending ENT department for Elective surgery

Full name of responsible person

Dr Rashada Farooqi

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Quid Avenue , Wah Cantt

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic International Medical College and Wah medical college

Full name of responsible person

Institutional Review Committee (IRC) Islamic International Medical College

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Grant name

No funding is provide except the permission to use the facility. All requirements for administration of drug and collecting, storing and centrifuging the blood samples till it reach for biochemical analysis

Grant code / Reference number

no

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

no

Proportion provided by this source

1

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**

Islamic International Medical College and Wah medical college

Full name of responsible person

Brig (R) Dr Akbar Waheed

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmacology and toxicology

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Person responsible for scientific inquiries

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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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

there is no further information

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable