

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 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

##### Phone

+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 variables 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, Peshawar 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 sugery

**Full name of responsible person**

Dr Rashada Farooqi

**Street address**

Quid Avenue , Wah Cantt

**City**

Wah Cantt

**Postal code**

47040

**Phone**

+92 314 5164991

**Fax**

+92 51 9314373

**Email**

dr.rashadafarooqi@gmail.com

**Web page address**

https://wahmedicalcollege.edu.pk/

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

Islamic International Medical College and Wah medical college

**Full name of responsible person**

Intsitutional Review Committee (IRC) Islamic International Medical College

**Street address**

276 Peshawer Road and Quid Avenue , Wah Cantt

**City**

Rawalpindi and Wah Cantt

**Postal code**

46000, 47040

**Phone**

+92 51 9094111

**Fax**

+92 51 9314373

**Email**

info@wahmedicalcollege.edu.pk

**Web page address**

https://wahmedicalcollege.edu.pk/

**Grant name**

No funding is provide excet the permission to use the facility.All requirments for administration of drug and collecting, storing and cetrifuging 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

**Street address**

276 Peshawer Road

**City**

Rawalpindi

**Province**

Punjab

**Postal code**

46000

**Phone**

+92 51 9094111

**Email**

akbar.waheed@riphah.edu.pk

**Web page address**

http://www.riphah.edu.pk

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Islamic International Medical College

**Full name of responsible person**

Prof Dr Akbar Waheed Brig(R)

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Pharmacology and Toxicology

**Street address**

276 Peshawer Road

**City**

Rawalpindi

**Province**

Punjab

**Postal code**

46000

**Phone**

+92 51 111 510 510

**Fax**

+92 51 5567527

**Email**

akbar.waheed@riphah.edu.pk

**Web page address**

<http://www.riphah.edu.pk>

## Person responsible for updating data

### Contact

**Name of organization / entity**

Wah Medical College--A project of POF Trust

**Full name of responsible person**

Dr Khalida Ajmal

**Position**

Professor

**Latest degree**

Master

**Other areas of specialty/work**

Pharmacology and Toxicology

**Street address**

Quid Avenue , Wah Cantt

**City**

Wah Cantt

**Province**

PUNJAB

**Postal code**

47040

**Phone**

+92 51 9094111

**Fax**

+92 51 9314373

**Email**

[info@wahmedicalcollege.edu.pk](mailto:info@wahmedicalcollege.edu.pk)

**Web page address**

<http://www.wahmedicalcollege.edu.pk>

## 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