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

Seadtion, Analgesia, Genotyping and Polymorphism in Receptor and enzyme determining the pharmakodynamic and pharmakokinetic of dexmeditomidine

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

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Khalida Ajmal
Name of organization / entity
Wah Medical College--A project of POF Trust
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Pakistan
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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
Dexmeditomidine 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 fullfiling the inclusion criteia, will be randomized into two groups by computer generated random numbers(Simple ramdomization) by assibning participants in control group with odd numbers and intervention group with even number. intervention Group will be administered 1µg/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 surgeryin 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 investgational drug. Half of the participants were inculded in cntrol 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
Intsitutional 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
Thr 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 neasea & vomiting.

Primary outcomes

1

Description
Intraoperative sedation and analgesia

Timepoint
beore interventiona 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 cam be studies both in control and study group in blood sample of 2hsr interval

Method of measurement
Drug concentration will be meausred 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 Farooqui
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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
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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
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Position
professor
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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