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Correlating the cough as a result of fentanyl injection while instituting general anaesthesia with the occurrence of nausea and vomiting after surgery in female patients

Submission date
30/12/2022

Recruitment status
No longer recruiting

Registration date
07/02/2023

Overall study status
Completed

Last Edited
30/01/2023

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to find any correlation between cough as a result of fentanyl injection during general anaesthesia and postoperative nausea and vomiting in female patients undergoing elective surgery.

Who can participate?
Female patients aged 18-59 years who are to undergo elective surgery lasting for 1- 3 hours under general anaesthesia

What does the study involve?
All female patients will be given general anaesthesia, during which fentanyl (2 mcg/kg) will be injected through an intravenous cannula (tube into a vein) over 10 seconds after 1 minute of premedication. The occurrence of any episode of cough within 60 seconds of fentanyl administration will be recorded as fentanyl-induced cough. All patients will be followed up for 24 hours after surgery for any occurrence of nausea and vomiting.

What are the possible benefits and risks of participating?
The study will improve our understanding of whether prevention of fentanyl-induced cough may help in alleviating postoperative nausea and vomiting, which is a common distressing symptom seen in patients after surgery. There are no life-threatening side effects associated with this study.

Where is the study run from?
St John's National Academy of Health Sciences (India)

When is the study starting and how long is it expected to run for?
September 2019 to November 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Sis Jose, sisjosevithayathil@gmail.com

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
01_M004_100390

Study information

Scientific Title
Correlation between fentanyl-induced cough (FIC) and postoperative nausea and vomiting (PONV) in female patients under general anaesthesia

Acronym
FICPONV

Study objectives

1. To find the correlation between fentanyl-induced cough (FIC) and postoperative nausea and vomiting (PONV) in female patients undergoing elective surgery under general anaesthesia
2. To find the incidence of fentanyl-induced cough in female patients undergoing elective surgery under general anaesthesia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/10/2019, Institutional Ethics Committee (Ground floor, St John's Medical College, Sarjapur Road, Bangalore - 560 034, India; +91 (0)80 49466346 / 48; sjmc.ierb@stjohns.in), ref: 305/2019

Study design
Single-center prospective observational study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Fentanyl-induced cough during general anaesthesia and postoperative nausea and vomiting in female patients

Interventions
Data is collected from adult female patients who come for elective surgeries under general anaesthesia from Sept 2019 - Sept 2021. All patients are nil per oral, 6 hours for solids and 2 hours for clear liquids. On arrival in the operating room, continuous ECG lead II, non-invasive arterial pressure, pulse oximetry and capnography monitoring are connected. Intravenous access is secured. All patients are preoxygenated and premedicated with glycopyrrolate 0.2mg, ondansetron 4 mg and midazolam 1 mg intravenously. Fentanyl is diluted with sterile water in a 10 ml syringe up to 20 mcg/ml. Fentanyl (2 mcg/kg) is injected through an i.v cannula over 10 seconds after 1 minute of premedication. An anaesthesiologist records the occurrence of any episode of cough within 60 seconds of fentanyl administration as fentanyl-induced cough. General anaesthesia is induced with propofol 1.5 - 2 mg/kg after cough cessation or 1 min after fentanyl injection. Atracurium, 0.5 mg/kg is used to facilitate tracheal intubation. Maintenance of anaesthesia is with isoflurane in an air–oxygen mixture. Morphine 0.1 mg/kg is administered for intraoperative analgesia. Upon completion of the procedure, the residual muscle relaxant effect is antagonized with neostigmine (50 mcg/kg) and glycopyrrolate (10 mcg/kg), and the volatile anaesthetic is discontinued. The trachea is extubated upon resumption of spontaneous

ventilation, and the patient is transferred to the recovery room. All postoperative assessments are made by observers blinded to whether the patient experienced fentanyl-induced cough or not. Patients who experience any degree of nausea or vomiting within the first 24 hours after surgery are classified as having PONV. The incidence and severity of patient complaints of nausea or vomiting within 24 hours of surgery are recorded by a trained nurse and treatment is given.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fentanyl, glycopyrrolate, midazolam, ondansetron, propofol, atracurium, morphine, neostigmine

Primary outcome measure
1. Fentanyl-induced cough is defined as the occurrence of any episode of cough within 60 seconds of intravenous fentanyl administration
2. Postoperative nausea and vomiting (PONV) is defined as any degree of nausea or vomiting within the first 24 hours after surgery, recorded on a score of 0, 1, or 2 (0 = no nausea or vomiting, 1 = tolerable nausea or vomiting, and 2 = intractable nausea or vomiting requiring medication)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
15/09/2019

Completion date
30/11/2021

Eligibility

Key inclusion criteria
1. Female patients aged 18-59 years
2. American Society of Anaesthesiologists (ASA) physical status 1 and 2
3. Surgery lasting for 1- 3 hours duration under general anaesthesia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit

59 Years

Sex
Female

Target number of participants
263

Total final enrolment
263

Key exclusion criteria
1. History of bronchial asthma or chronic obstructive pulmonary disease
2. Smoking status
3. Respiratory or gastrointestinal infection in the previous 2 weeks
4. Preoperative use of an angiotensin-converting enzyme inhibitor, an antiemetic, a bronchodilator or a steroid
5. History of PONV or motion sickness
6. Laparoscopic surgeries
7. Surgeries for malignant lesions

Date of first enrolment
01/11/2019

Date of final enrolment
01/11/2021

Locations

Countries of recruitment
India

Study participating centre
St. John's National Academy of Health Sciences
Sarjapur Road
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Sponsor information

Organisation
St. John's National Academy of Health Sciences

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Sponsor type
Hospital/treatment centre

Website
http://www.stjohns.in/

ROR
https://ror.org/03qvjzj64

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/04/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality rights.

IPD sharing plan summary
Not expected to be made available