

# 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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/02/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 30/01/2023	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

### Contact name

Dr Sis Jose

### ORCID ID

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### Contact details

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Prevention

**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(s)**

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)

**Key secondary outcome(s)**

There are no secondary outcome measures

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

59 years

**Sex**

Female

**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

Karnataka

Bangalore

India

560034

## Sponsor information

**Organisation**

St. John's National Academy of Health Sciences

**ROR**

<https://ror.org/03qvjzj64>

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

**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