

# Prevalence and predictors of complications during sedation for paediatric gastrointestinal endoscopy

<b>Submission date</b> 28/12/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/01/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/11/2020	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A gastrointestinal endoscopy is a procedure which allows a doctor to see the inside of the digestive tract. It is performed using a thin flexible tube with a tiny video camera on the end (an endoscope), which is passed down the throat into the stomach. It is one of the most commonly performed procedures in children, which requires deep sedation (general anaesthesia). The use of general anaesthesia in children can, in some cases, lead to complications with breathing. The aim of this study is to find out whether there are any common characteristics in children that can be used to predict whether they are likely to have breathing complications after having a gastrointestinal endoscopy procedure.

### Who can participate?

Children aged 16 years and under who had a gastrointestinal endoscopy between January 2010 and August 2016.

### What does the study involve?

Medical records of all children aged 16 years and under who had a gastrointestinal endoscopy as part of their usual care between January 2010 and August 2016 are retrieved from the hospital's medical registry. The medical records are then reviewed in order to find out background information about the children, information about what the procedure found and whether anything went wrong, information about the sedation used and whether there were any breathing complications after the procedure. This information is then used to find out whether children who had breathing complications have anything in common that can be used to flag up these cases in the future.

### What are the possible benefits and risks of participating?

There are no direct benefits or risks involved to those participating.

### Where is the study run from?

Universitair Ziekenhuis Brussel (Belgium)

When is the study starting and how long is it expected to run for?  
March 2016 to April 2017

Who is funding the study?  
Universitair Ziekenhuis Brussel (Belgium)

Who is the main contact?  
1. Mrs Veerle Van Mossevelde (public)  
2. Dr Nadia Najafi (scientific)

## Contact information

**Type(s)**  
Public

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## Additional identifiers

**Protocol serial number**  
PSA-GI 01

## Study information

**Scientific Title**  
Prevalence and predictors of adverse respiratory events during deep sedation using native airway for paediatric gastrointestinal endoscopy in lateral position

**Study objectives**

An accurate risk assessment prior to the paediatric gastrointestinal endoscopy would enable the anaesthesiologists to reduce the likelihood of respiratory complications.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Commissie Medische Ethiek (O.G. 016) Reflectiegroep Biomedische Ethiek, 08/02/2017, ref: 2016/418

### **Study design**

Single-centre retrospective cohort study

### **Primary study design**

Observational

### **Study type(s)**

Prevention

### **Health condition(s) or problem(s) studied**

Respiratory complications

### **Interventions**

Medical records of all children up to the age of 16 years who required in- or outpatient procedural deep sedation and analgesia between January 1, 2010 and August 31, 2016 will be retrieved from the hospital's medical registry. The medical records of all these cases will be reviewed to identify those who underwent an elective or diagnostic gastrointestinal endoscopy. Demographic data, procedural data and anaesthetic data is then extracted. The type and timing of occurrence of adverse respiratory events will be reviewed from the initiation of the sedation procedure until 24 hours later.

### **Intervention Type**

Other

### **Primary outcome(s)**

Prevalence and predictors of respiratory complications during paediatric gastrointestinal endoscopy in lateral position is assessed through medical record review at the end of the study.

### **Key secondary outcome(s)**

1. Association between the type of sedative(s) used, dosage of induction agents administered and the adverse respiratory event experience is assessed through medical record review at the end of the study
2. Most appropriate induction dose of sedative(s) in normal- weight (mg per kg current body weight), obese and morbidly obese children (mg per kg current body weight and mg per kg ideal body weight) is assessed through medical record review at the end of the study
3. Ease of performing the procedure as satisfactory, difficult or impossible and the reason for this is assessed through medical record review at the end of the study
4. Failure rate and reason of this (e.g. inappropriate sedation or complications) is assessed through medical record review at the end of the study
5. Prevalence of post procedural nausea, vomiting and agitation is assessed through medical record review at the end of the study

6. Sedation time (time required to complete procedures), time to recovery and time to discharge is assessed through medical record review at the end of the study
7. Prevalence of any unplanned escalation of care e.g. transfer from the ward to the paediatric intensive care unit or prolonged hospitalization is assessed through medical record review at the end of the study

**Completion date**

20/04/2017

## Eligibility

**Key inclusion criteria**

1. Children up to the age of 16 years
2. Required in- or outpatient procedural deep sedation and analgesia for an elective or diagnostic gastrointestinal endoscopy between January 1, 2010 and August 31, 2016

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Upper age limit**

16 years

**Sex**

All

**Total final enrolment**

3435

**Key exclusion criteria**

1. Children presenting with an American Society of Anaesthesiologists physical status classification  $\geq$  IV
2. Ventilated children
3. Children already receiving sedative medications prior to sedation procedure
4. Children requiring therapeutic or urgent gastrointestinal endoscopy

**Date of first enrolment**

20/04/2016

**Date of final enrolment**

31/12/2016

## Locations

**Countries of recruitment**

Belgium

**Study participating centre**  
**Universitair Ziekenhuis Brussel**  
Laarbeeklaan 101  
Brussel  
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1090

## Sponsor information

**Organisation**  
Universitair Ziekenhuis Brussel

**ROR**  
<https://ror.org/038f7y939>

## Funder(s)

**Funder type**  
Hospital/treatment centre

**Funder Name**  
Universitair Ziekenhuis Brussel

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from [nadia.najafi@uzbrussel.be](mailto:nadia.najafi@uzbrussel.be)

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2019	27/11/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes