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Prevalence and predictors of complications during sedation for paediatric gastrointestinal endoscopy

Submission date
28/12/2016

Recruitment status
No longer recruiting

Registration date
20/01/2017

Overall study status
Completed

Last Edited
27/11/2020

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact name
Mrs Veerle Van Mossevelde

Contact details
Universitair Ziekenhuis Brussel
Laarbeeklaan 101
Brussels
Belgium
1090

Type(s)
Scientific

Contact name
Dr Nadia Najafi

Contact details
Laarbeeklaan 101
Brussels
Belgium
1090

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 extrated. 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 measure

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.

Secondary outcome measures
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

Overall study start date
20/03/2016

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

Age group
Child

Upper age limit
16 Years

Sex
Both

Target number of participants
3000

Total final enrolment
3435

Key exclusion criteria
1. Children presenting with an American Society of Anaesthesiologists physical status classification ≥ 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
Belgium
1090

Sponsor information

Organisation
Universitair Ziekenhuis Brussel

Sponsor details
Laarbeeklaan 101
Brussels
Belgium
1090

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/038f7y939

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitair Ziekenhuis Brussel

Results and Publications

Publication and dissemination plan
The results of this study may be incorporated in the subsequent studies and it is intended to be published in a high-impact peer reviewed journal..

Intention to publish date
31/12/2018

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

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2019	27/11/2020	Yes	No