ISRCTN12921661 https://doi.org/10.1186/ISRCTN12921661

Does a propofol or sevoflurane based protocol has an effect on bowel motility during laparosopic surgery.

Submission date
03/07/2015

Recruitment status
No longer recruiting

Registration date
19/08/2015

Overall study status
Completed

Last Edited
26/01/2016

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
During laparoscopic surgery, small bowel paralysis facilitates surgical conditions. This is especially important when complex surgery, with intestinal suturing or stapling, is performed. Both opioids and hypnotic agents might influence small bowel peristalsis. The effects of opioids on intestinal motility (intestinal contractions) are well studied and are known to result in intestinal paralysis. With reference to the effects of hypnotics on intestinal motility, data are scarce. Our group recently studied the effect of different volatile (inhaled) anaesthetics on intestinal motility during laparoscopic surgery requiring small bowel anastomosis (removal of a piece of bowel followed by the joining up of the remaining sections). There were statistically significant less peristaltic waves (involuntary muscle movements in the bowel) in the sevoflurane-based anaesthesia group compared to the desflurane-based anaesthesia group. Stimulation of the irritant Transient Receptor Potential channel A1 (TRPA1) was offered to explain the increased intestinal motility observed with desflurane compared to sevoflurane. Given the fact that propofol is a direct modulator of TRPA1, we hypothesized that propofol increases intestinal motility during anaesthesia compared to sevoflurane.

Who can participate?
All patients presenting for gastric bypass surgery at the AZ Groeninge Hospital

What does the study involve?
Patients are randomized in two study groups. One group receives a propofol based anesthesia and one group receives a sevoflurane based anesthesia. At a specific time point during surgery, intestinal motility is assessed by the surgeon and scrub nurse.

What are the possible benefits and risks of participating?
Benefits include an advancement in better understanding of the effects of anesthetics on intestinal motility. No risks are involved in participating in the study, besides the risk involved with anesthesia and surgery.

Where is the study run from?
AZ Groeninge Hospital, Kortrijk (Belgium)

When is the study starting and how long is it expected to run for?
April 2013 to December 2013

Who is funding the study?
AZ Groeninge Hospital (Belgium)

Who is the main contact?
Matthias Desmet

Contact information

Type(s)
Public

Contact name
Dr Matthias Desmet

Contact details
Loofstraat 43
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AZG 2013017

Study information

Scientific Title
The effect of propofol and sevofurane on intestinal motility during laparoscopic surgery: a single blind randomized controlled trial.

Study objectives
Propofol anaesthesia increases intestinal motility during laparoscopic gastric bypass surgery compared to sevoflurane based anaesthesia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
AZ Groeninge Ethical Committee, 04/03/2013, ref: 13006

Study design
Single-centre prospective randomized controlled single-blind two-arm interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

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

Health condition(s) or problem(s) studied
Observation of intestinal motility during laparoscopic surgery

Interventions
2-arm study:
1. Group TIVA (Total Intravenous Anesthesia) will receive a propofol based anesthesia
2. Group Sevo will receive a sevoflurane based anesthesia

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
1. Propofol 2. Sevoflurane

Primary outcome measure
Intestinal motility measured by visual count of peristaltic waves

Secondary outcome measures
N/A

Overall study start date
01/10/2012

Completion date
01/06/2014

Eligibility

Key inclusion criteria
All patients presenting for laparoscopic Roux en Y bariatric surgery at AZ Groeninge Hospital

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
25/group

Key exclusion criteria
Redo surgery

Date of first enrolment
01/04/2013

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Belgium

Study participating centre
AZ Groeninge
Loofstraat 43
8500 Kortrijk
Kortrijk
Belgium
8500

Sponsor information

Organisation
Dpt Anesthesia, AZ Groeninge

Sponsor details
Loofstraat 43
Kortrijk
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8500

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01cz3wf89

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Anesthesia, AZ Groeninge Hospital (Belgium)

Results and Publications

Publication and dissemination plan
Publication in Peer reviewed Anaesthesia Journal (eg. Acta Anaesthesiologica Scandinavica)

Intention to publish date
01/09/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No