

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

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<b>Registration date</b> 19/08/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/01/2016	<b>Condition category</b> Surgery	<input type="checkbox"/> 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  
Kortrijk  
Belgium  
8500

## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Not Specified

**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(s)**

Intestinal motility measured by visual count of peristaltic waves

**Key secondary outcome(s)**

N/A

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

**ROR**

<https://ror.org/01cz3wf89>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Department of Anesthesia, AZ Groeninge Hospital (Belgium)

## **Results and Publications**

**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?
<a href="#">Results article</a>	results	01/03/2016		Yes	No