

# Effects of thoracic analgesia on gastrointestinal motility

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<b>Registration date</b> 20/03/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/10/2017	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

After undergoing surgery, especially abdominal (belly) surgery, patients experience a decrease in their gut function that results in constipation, bloating, nausea and vomiting. The cause of this is still unclear but surgical manipulation of the gut, medical assessments, and medication given for pain control after surgery have been shown to contribute. This study explores the effect of different pain control regimes on the function of the gut following thoracic (lung) surgery. The aim of this study is to look at the effects of morphine delivered through a drip, local anaesthetics (numbing agents) delivered directly into the spine (epidural catheter) and a combination of the two techniques on gut function and pain after surgery.

### Who can participate?

Adults aged 30-85 who are undergoing major thoracic surgery

### What does the study involve?

One week before having surgery, all patients undergo two tests of gut function. The first involves measuring the time it takes for a substance to travel from the mouth to the beginning on the large intestine. In the second test, patients are asked to swallow 20 small plastic pellets that are visible by x-ray of their abdomen. They then have an x-ray four days later in order to measure how many of them are left in their large bowel, to give an indication of the time that the large bowel needs to empty. On the day of surgery, participants are randomly allocated to one of three groups. Participants receive surgery and surgical aftercare as normal. Those in the first group have a tube inserted into their spine through which numbing agents are delivered to provide pain relief. Those in the second group receive a combination of morphine (a strong pain killer) and a numbing agent through a drip. Those in the third group receive a combination of the techniques given to those in the first two groups. In the days following surgery, participants are asked to rate their pain levels and repeat the gut function tests taken one week before their surgery.

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

Participants benefit from being enrolled in a standardised recovery programme which could help

enhance their recovery. There is a small risk of experiencing side-effects from the medications used in this study to control pain, such as low blood pressure, nausea and vomiting, drowsiness, or allergic reaction.

Where is the study run from?

University Hospital of Heraklion (Greece)

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

September 2001 to November 2009

Who is funding the study?

1. University Hospital of Heraklion (Greece)
2. Investigator initiated and funded (Greece)

Who is the main contact?

Dr Argyro Zoumprouli

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

3197

## Study information

**Scientific Title**

Gastrointestinal motility following thoracic surgery, the effect of thoracic epidural analgesia: a randomised controlled trial

**Study objectives**

Epidural analgesia accelerates the postoperative gastrointestinal function compared with IV morphine following major thoracic surgery.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics committee of the University Hospital of Heraklion, 19/03/2002, ref: 3197

**Study design**

Single-centre unblinded three-arm randomised parallel trial

**Primary study design**

Interventional

**Secondary study design**

Randomised parallel trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet (in Greek)

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

Gastrointestinal motility after major thoracic surgery

**Interventions**

All patients have a standard preoperative assessment and received teaching on how to score pain and to report side effects. In addition, they are informed about postoperative tests, feeding and early ambulation, as well as postoperative visits from different teams. One hour before surgery, all patients receive premedication with intramuscular 0.07 mg.kg<sup>-1</sup> midazolam. On arrival to the anaesthetic room, each patient is randomised by a computer-generated list of random numbers to one of three groups.

Group Ep-R: Participants receive a continuous epidural infusion of ropivacaine 0.2% (2 mg.ml<sup>-1</sup>) at a rate of 5-8 ml.h<sup>-1</sup>, with boluses of 2 ml of the same solution and a 20 min lockout interval via a PCA

Group Ep-RM: Participants receive a continuous epidural infusion of ropivacaine 0.15% (1.5 mg.ml<sup>-1</sup>) with morphine 0.05 mg.ml<sup>-1</sup> at a rate of 5-7 ml.h<sup>-1</sup>, with boluses of 2 ml of the same solution and a 20 min lockout interval via a PCA

Group IV-M: Participants receive a continuous IV infusion of morphine of 1 mg.ml<sup>-1</sup>.h<sup>-1</sup>, with boluses of 0.5-1 mg and a 15 min lockout interval via a PCA

In groups Ep-R and Ep-RM before induction of general anaesthesia, a 20 G epidural catheter is inserted through an 18 G Tuohy needle between the T5-T9 levels using the loss of resistance technique and is threaded 3-5 cm into the epidural space.

Gastrointestinal motility is assessed for all participants by measuring oro-caecal transit time (exhaled H<sub>2</sub>-lactulose test) and colonic transit time (radiopaque markers). Oro-cecal transit time (OCTT) is evaluated using the lactulose hydrogen (H<sub>2</sub>) breath test the first and third postoperative day. Colonic transit time (CTT) is evaluated by plain abdominal radiograph taken 4 days after the ingestion of 20 radiopaque markers. The indigestion of the markers takes place on the first postoperative morning. All patients participate in a standardised post-operative recovery regiment (early feeding, early ambulation).

### **Intervention Type**

Drug

### **Drug/device/biological/vaccine name(s)**

1. Ropivacaine 2. Morphine

### **Primary outcome measure**

1. Orocecal transit time is assessed using the lactulose H<sub>2</sub> test on post-operative days 1 and 3
2. Colonic transit time is assessed by radiopaque markers and abdominal X-rays on post-operative day 4

### **Secondary outcome measures**

Pain is measured using a visual analogue scale (VAS) on post-operative days 1 and 3

### **Overall study start date**

02/09/2001

### **Completion date**

10/11/2009

## **Eligibility**

### **Key inclusion criteria**

1. Undergoing major thoracic surgery
2. Age 30-85 years

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

**Target number of participants**

30 patients in total, 10 in each of three groups

**Key exclusion criteria**

1. Diabetes mellitus
2. ASA physical status >III
3. History of chronic pain
4. Drug/alcohol dependence
5. Treatment with drugs known to affect GI motility
6. Inflammatory bowel disease
7. Previous bowel surgery
8. Morphine or local anaesthetic allergy
8. History of abdominal radiation
9. Contraindications to insertion of an epidural catheter
10. Severe renal or hepatic disease

**Date of first enrolment**

20/03/2002

**Date of final enrolment**

22/01/2009

**Locations****Countries of recruitment**

Greece

**Study participating centre**

University Hospital of Heraklion

Voutes

Voutes

Greece

71500

**Sponsor information****Organisation**

University Hospital of Heraklion

**Sponsor details**

Anaesthesiology Department

Voutes

Heraklion

Greece

71500

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/0312m2266>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

University Hospital of Heraklion

**Funder Name**

Investigator initiated and funded

## Results and Publications

**Publication and dissemination plan**

Planned publication in a peer reviewed journal.

**Intention to publish date**

01/01/2018

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Argyro Zoumprouli (Argyro.Zoumprouli@stgeorges.nhs.uk)

**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	16/10/2017		Yes	No