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Effects of thoracic analgesia on gastrointestinal motility

Submission date 04/03/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/03/2017	**Overall study status** Completed	
Last Edited 19/10/2017	**Condition category** Digestive System	

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 vomitting, 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 Hosipital 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

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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-1 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-1) at a rate of 5-8 ml.h-1, 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-1) with morphine 0.05 mg.ml-1 at a rate of 5-7 ml.h-1, 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-1.h-1, 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 orocaecal transit time (exhaled H2-lactulose test) and colonic transit time (radiopaque markers). Oro-cecal transit time (OCTT) is evaluated using the lactulose hydrogen (H2) 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. Oroceacal transit time is assessed using the lactulose H2 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 dependance
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
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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?
Results article	results	16/10/2017		Yes	No