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Epidural Analgesic Therapy (EAT) versus IntraVenous patient-controlled Analgesia (IVA)

Submission date 10/06/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/08/2009	**Overall study status** Completed	
Last Edited 04/08/2009	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CDI-00301-2009

Study information

Scientific Title

Epidural analgesia in video laparoscopic (VL) left hemicolectomy - optional and not mandatory choice in "Fast Track" treatment: a randomised controlled trial

Acronym
EAT IVA

Study objectives
Randomised trial conducted in order to quantify the concrete validity and limitations of intravenous patient-controlled analgesia therapy (IVA) versus epidural analgesic therapy (EAT) in "Fast Track" treatment of patients submitted to video laparoscopic left hemicolectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval not required as the comparison in this trial was between two non-experimental procedures.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Colorectal cancer

Interventions
After VL left hemicolectomy, patients would be provided analgesia in one of two ways: intravenous patient-controlled analgesia therapy (IVA) versus epidural analgesic therapy (EAT).

The following drugs were used:
IVA: Tramadol (400 mg/day), Ketoprofene (320 mg/day), Morphine (20 mg/day), Metoclopramide (20 mg/day), Ropivacaine cloridrate (12 - 28 mg/hour continuous infusion)
EAT: via epidural catheter (Naropine)

The average duration of treatment was 3.07 days for the IVA group and 4.05 days for the EAT group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Pain control, measured with the Visual Analogue Scale (VAS) at day 0,1 and 2

Secondary outcome measures
1. Canalisation, measured daily
2. Drainage removal, measured daily

Overall study start date
01/01/2007

Completion date
30/04/2009

Eligibility

Key inclusion criteria
1. Patients with neoplastic or recurrent flogistic pathology of the left colon
2. Patients with indication to VL surgery
3. Aged less than 18 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Patients over 80 years old
2. American Society of Anaesthesiologists (ASA) grade 4

Date of first enrolment
01/01/2007

Date of final enrolment

30/04/2009

Locations

Countries of recruitment
Italy

Study participating centre
Via Alfieri 16
Milano
Italy
20154

Sponsor information

Organisation
Lecco Hospital Corporation (Azienda Ospedaliera Ospedale di Lecco) (Italy)

Sponsor details
Presidio di Merate Leopoldo Mandic
Merate
Italy
23900

Sponsor type
Hospital/treatment centre

Website
http://www.ospedale.lecco.it/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Italy)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration