ISRCTN79187946 https://doi.org/10.1186/ISRCTN79187946

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
1. Canalisation, measured daily
2. Drainage removal, measured daily

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration