

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

Submission date 10/06/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/08/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 04/08/2009	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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