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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Contact information

Type(s)

Scientific

#### Contact name

Dr Pierpaolo Caputo

#### Contact details

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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

# Locations

#### Countries of recruitment

Italy

## Study participating centre Via Alfieri 16 Milano

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