# Post-operative inflammatory and angiogenic response in patients with resectable colon cancer: a randomised clinical trial comparing open versus laparoscopic surgery

Submission date	Recruitment status No longer recruiting	Prospectively registered	
02/07/2009		<pre>Protocol</pre>	
Registration date	Overall study status Completed	Statistical analysis plan	
19/08/2009		[X] Results	
Last Edited	Condition category	[] Individual participant data	
27/01/2011	Cancer		

## Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Miguel Pera

#### Contact details

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# Additional identifiers

## Protocol serial number

001

# Study information

#### Scientific Title

Randomised clinical trial of the inflammatory and angiogenic responses of open and laparoscopic surgery for colon cancer

## **Acronym**

**ARALOS** 

## **Study objectives**

The increased inflammatory response in patients with colon cancer undergoing open resection compared with laparoscopic surgery is associated with an increased angiogenic response.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Hospital del Mar Comité Ético de Investigación Clínica (IRB) approved in June 2003 (reference number 2003/1621/I)

## Study design

Randomised controlled two-arm trial

## Primary study design

Interventional

# Study type(s)

Treatment

# Health condition(s) or problem(s) studied

Colon cancer

#### **Interventions**

Patients are randomised to either laparoscopic or open colectomy. Serum and peritoneal fluid samples are obtained at baseline, 12, 24 and 48 hours and post-operative day 4. Peritoneal fluid samples are obtained through an aspirative drain.

## Intervention Type

Other

#### Phase

Not Applicable

## Primary outcome(s)

- 1. Post-operative vascular endothelial growth factor (VEGF) serum and peritoneal fluid levels
- 2. Post-operative platelet derived growth factor (PDGF) serum and peritoneal fluid levels
- 3. Microvascular density determined in serum and peritoneal fluid on in vitro angiogenesis assay
- 4. Capillary length determined in serum and peritoneal fluid on in vitro angiogenesis assay

Samples obtained at baseline, 12, 24 and 48 hours and post-operative day 4.

## Key secondary outcome(s))

- 1. Levels of pro-inflammatory cytokines interleukin-6 (IL-6) and interleukin-1 beta (IL-1 beta) determined in serum and peritoneal fluid
- 2. Correlation between pro-inflammatory and angiogenic cytokines

Samples obtained at baseline, 12, 24 and 48 hours and post-operative day 4.

## Completion date

31/12/2007

# **Eligibility**

## Key inclusion criteria

- 1. Patients with resectable colon cancer, either sex
- 2. Written informed consent
- 3. Aged older than 18 years

## Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

#### Sex

All

## Key exclusion criteria

- 1. Patients with metastasic disease
- 2. Patients with locally advanced colon cancer
- 3. Patients undergoing emergency surgery
- 4. Transverse colon and splenic flexure cancer
- 5. Patients with a second neoplasm

## Date of first enrolment

01/06/2004

## Date of final enrolment

31/12/2007

# Locations

## Countries of recruitment

Spain

Study participating centre Colorectal Surgery Unit Barcelona Spain 08003

# Sponsor information

## Organisation

Hospital del Mar (Spain)

## **ROR**

https://ror.org/03a8gac78

# Funder(s)

## Funder type

Government

## **Funder Name**

Spanish Ministry of Health, Investigation of Sanitary Funding (Fondo de Investivación Sanitaria Ministerio de Sanidad y Consumo) (Spain)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created Date added	Peer reviewed	Patient-facing?
Results article	results	01/01/2011	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	i No	Yes