

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

<b>Submission date</b> 02/07/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/01/2011	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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 metastatic 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 Investigación 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?
<a href="#">Results article</a>	results	01/01/2011		Yes	No