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

Submission date
02/07/2009

Registration date
19/08/2009

Last Edited
27/01/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/06/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

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)

Sponsor details
Passeig Maritim 25 - 29
Barcelona
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+34 63 97 64 484
mpera@imas.imim.es

Sponsor type
Hospital/treatment centre

Website
http://www.hospitaldelmar.cat

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2011		Yes	No