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Robotic Surgery in ColoRectal Cancer

Submission date 09/01/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/01/2010	**Overall study status** Completed	
Last Edited 11/01/2012	**Condition category** Cancer	

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
N/A

Study information

Scientific Title
Robotic-assisted laparoscopic surgery versus conventional laparoscopic surgery in colorectal carcinoma resection: a prospective randomised study

Acronym

RSCRC

Study objectives
To analyse the safety and efficacy of robot-assisted laparoscopic surgery (Da Vinci) versus conventional laparoscopy in colorectal surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hospital Clinical Trials and Ethics Committee of the University Hospital Virgen del Rocio and the Technology Assessment Agency Government of the Junta de Andalucia approved of this trial in 2007

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Colorectal carcinoma

Interventions
Following confirmation of the inclusion criteria, patients will be randomised by computer. Patients will be randomised in two groups according to whether patients underwent a colectomy with robotic assistance or not. Robotic surgery will be performed by three laparoscopic experienced surgeons of the Surgery Department of HU Virgen del Rocio. Specific training in robotic surgery was done in a specialised centre for training (IRCAD, Strasbourg). Laparoscopic interventions will be performed by two surgeons who also had extensive experience in laparoscopic colorectal surgery.The surgical technique will be similar in both groups.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Morbidity and mortality. Parameters will be determined during operation and in the post-operative time.

Key secondary outcome(s))
Oncologic determinations:
1. Size of resection

2. Distance to the resection margin
3. Lymphatic nodes
4. Post-operative staging

Parameters will be determined during operation and in the post-operative time.

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Tumours located in sigmoid colon or rectosigmoid junction
2. Patients younger than 80 years, either sex
3. Patients with American Society of Anaesthesiologists (ASA) grade not superior to III
4. Patients with body mass index (BMI) less than 30 kg/m^2

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Stage IV tumours

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Spain

Study participating centre
Servicio de Cirugia General
Sevilla
Spain
41013

Sponsor information

Organisation
Virgen del Rocio University Hospital (Hospital Universitario Virgen del Rocío) (Spain)

ROR
https://ror.org/04vfhnm78

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Virgen del Rocio University Hospital (Hospital Universitario Virgen del Rocío) (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	01/08/2011		Yes	No