

Robotic Surgery in ColoRectal Cancer

Submission date 09/01/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/01/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/01/2012	Condition category Cancer	☐ 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

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

Primary study design

Interventional

Study design

Prospective randomised controlled trial

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/m²

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/04vfhn78>

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