

# Robotic Surgery in ColoRectal Cancer

<b>Submission date</b> 09/01/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/01/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/01/2012	<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

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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<sup>2</sup>

**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?
<a href="#">Results article</a>	results	01/08/2011		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes