

The influence of two policies of closure of the laparotomy wound in the rate of surgical site infection in colorectal cancer surgery: the New Operation trial

Submission date 15/05/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/06/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/04/2012	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

09/01; PI08/90196

Study information

Scientific Title

A prospective double blinded randomised multicentre trial of the influence of two policies of closure of the laparotomy wound in the rate of surgical site infection in colorectal cancer surgery

Acronym

NewOp

Study objectives

A decreased faecal load in the surgical wound diminished the incidence of surgical site infection.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Medical Ethics Committee of the Virgen del Camino Academic Medical Centre, Pamplona gave approval on the 7th May 2009 (ref: 6/2008). Under Spanish law, all other centres will be included under this approval.

Study design

Prospective double blinded randomised multicentre 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

Colorectal cancer

Interventions

Control group: at the end of the operation the nurses and surgeons will change gloves, a new set of surgical instruments will be used and the surgical drapes surrounding the laparotomy will be changed.

Study group: at the end of the operation and before closing the laparotomy; the surgical assistant will retire all the surgical drapes and the surgeon will retire the plastic coverage of the wound and the wound will be covered with a povidone-soaked gauze. Nurse and surgical teams will scrub again and the surgical instruments will be changed.

Total duration of follow-up: one month after the recruitment of the last patient.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Incidence of surgical site infection. The criteria to define surgical site infection are described by Disease Control and Prevention National Healthcare Safety Network (Spain). For the purposes of this study superficial and deep wound infections would be considered as a unique entity condition. This will be measured 30 days after the operation.

Secondary outcome measures

The relationship between wound infection rate and the following variables:

1. Age
2. Sex
3. Location of the tumour (colon/rectum)
4. TNM stage
5. Obesity
6. Level of glucose
7. Long course radiotherapy

Measured 30 days after the operation.

Overall study start date

01/06/2009

Completion date

01/06/2011

Eligibility

Key inclusion criteria

1. Aged above 18 years, either sex
2. Colon and rectal cancer

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

738

Key exclusion criteria

1. Before the enrolment: emergency surgery
2. At enrolment:
 - 2.1. Not willing to participate
 - 2.2. Non-resectable tumours
 - 2.3. Multi-visceral resection planned
 - 2.4. Recurrence of colon or rectal carcinoma
 - 2.5. Laparoscopic abdominoperineal resection
 - 2.6. Patients programmed to place a mesh simultaneously for an incisional hernia
3. At allocation:
 - 3.1. Non-resectable tumours
 - 3.2. The surgeon decides to prescribe antibiotics due to faecal contamination during operation
 - 3.3. Any violation of the protocol
4. At follow-up:
 - 4.1. Peri-operative mortality
 - 4.2. Patients reoperated for any reason in the first 30 days after primary surgery
 - 4.3. Patients with an organ/space infection draining through the wound
 - 4.4. Patients not followed for at least 30 days after surgery

Date of first enrolment

01/06/2009

Date of final enrolment

01/06/2011

Locations

Countries of recruitment

Spain

Study participating centre

Hospital Virgen del Camino

Pamplona

Spain

31008

Sponsor information

Organisation

Carlos III Institute of Health (Instituto de Salud Carlos III) (Spain)

Sponsor details

C/ Sinesio Delgado 4 - 6 (entrada por Avda. Monforte de Lemos, 5.)

Madrid

Spain

28029

Registro.general@isciii.es

Sponsor type

Research organisation

Website

<http://www.isciii.es/htdocs/index.jsp>

ROR

<https://ror.org/00ca2c886>

Funder(s)**Funder type**

Research council

Funder Name

Spanish National Research Council (Consejo Superior de Investigaciones Cientificas [CSIC]) (Spain)

Alternative Name(s)

Spanish National Research Council, El Consejo Superior de Investigaciones Científicas (CSIC), CSIC, elcsic

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

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	01/07/2012		Yes	No