

Enhanced recovery in colorectal surgery: a multicentre study from the Spanish Working group

Submission date 19/09/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/10/2010	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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San Juan Bosco 15
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50009

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

A multicentre prospective interventional study from the Spanish Working group into enhanced recovery in colorectal surgery

Study objectives

The implementation of an enhanced recovery after surgery protocol in major colorectal surgery reduces postoperative complications and hospital stays.

Ethics approval required

Old ethics approval format

Ethics approval(s)

No specific ethical requirements for this study; informed by Hospital Ethical Board that ethics approval was not required as this is an observational non-randomised study based on the best available evidence.

Study design

Observational non-randomised study

Primary study design

Observational

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please contact ard-fast-track@googlegroups.com to request a patient information sheet

Health condition(s) or problem(s) studied

Colorectal disease

Interventions

Colorectal surgery

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Morbi-mortality, measured from operation to two months after surgery

Secondary outcome measures

Hospital stay, measured from operation up to release from hospital

Overall study start date

01/01/2008

Completion date

31/08/2010

Eligibility

Key inclusion criteria

1. Aged 18 years or over, either sex
2. Programmed for surgery for colorectal cancer without the need for a stoma or any further surgical procedure

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

300

Key exclusion criteria

1. Need for emergency surgery
2. American Society of Anaesthesiologists (ASA) class IV
3. Need for a colostomy or ileostomy
4. Inability to provide informed consent
5. Diabetes
6. Slow evacuation previously documented by a digestive medicine unit

Date of first enrolment

01/01/2008

Date of final enrolment

31/08/2010

Locations

Countries of recruitment

Spain

Study participating centre

Servicio de Cirugia

Zaragoza

Spain

50009

Sponsor information

Organisation

Spanish Working Group on Multimodal Rehabilitation (Grupo Español de Rehabilitacion Multimodal [GERM]) (Spain)

Sponsor details

Servicio de Cirugia

Hospital Clinico Universitario

San Juan Bosco 15

Zaragoza

Spain

50009

Sponsor type

Research organisation

Website

<http://ftsurgery.com/>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (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