

The effect of enhanced pre-operative information on patient recovery following colorectal surgery: a randomised controlled trial.

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/02/2014	Condition category Surgery	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0084151426

Study information

Scientific Title

Study objectives

1. To assess the acceptability and psychological effects of fast-track surgery
2. To perform an economic analysis of fast-track surgery
3. To examine the role of enhanced pre-operative information in fast-track surgery
4. To examine the relationship between the stress response and length of stays

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Surgery: Colorectal

Interventions

Recruitment for this study will occur in consecutive patients attending preassessment clinics. Randomisation will be performed at a remote site and accessed by telephone. A computer generated permuted block randomisation technique will be employed.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

1. Psychological effects and acceptability will be assessed by Hospital Anxiety and Depression Score (HADS).
2. The economic analysis will be based on the EuroQol.
3. The RCT will be assessed by 6 item Spielberger anxiety inventory
4. Physiological stress will be assessed by salivary IgA levels

Secondary outcome measures

Not provided at time of registration

Overall study start date

07/09/2004

Completion date

01/08/2007

Eligibility

Key inclusion criteria

1. Age over 16
2. Undergoing colorectal resections or colostomy/ileostomy formation or closure

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

Minimum of 15 patients

Key exclusion criteria

1. Visual impairment
2. Inadequate comprehension to understand pre-op information and sign consent form

Date of first enrolment

07/09/2004

Date of final enrolment

01/08/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Castle Hill Hospital
Cottingham
United Kingdom
HU16 5JQ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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SW1A 2NL
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Sponsor type
Government

Website
<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type
Government

Funder Name
The North and South Bank Research and Development Consortium

Funder Name
NHS R&D Support Funding

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