ISRCTN81232818 https://doi.org/10.1186/ISRCTN81232818

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

Registration date
30/09/2005

Overall study status
Completed

Last Edited
04/02/2014

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Surgery: Colorectal

Interventions
Recruitment for this study will occur in consecutive patients attending preassesment 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(s)
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

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration