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Early reversal of defunctioning ileostomy

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 19/09/2016	**Condition category** Surgery	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0077155741

Study information

Scientific Title
Early reversal of defunctioning ileostomy

Study objectives
We hypothesize that early reversal of a defunctioning stoma reduces the cost of stoma care and related complications. We expect the quality of life of those patients who have early reversal will be better that those patients who have a late reversal. We also expect the total time spent in hospital to be reduced.

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)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
Participants will be randomly allocated to either the treatment or control group and to one of the subsets by block randomization. Subjects may withdraw their consent at any time and consequently leave the study. Investigator led withdrawal will occur where there is evidence of non-compliance with protocol requirements.
Even if subjects are withdrawn prematurely from the study survival data on such subjects will be collated throughout the protocol defined follow-up period for that subject. Those that fail to attend follow up clinics will be contacted by telephone. The patients normal medications are permitted to continue during the course of the study.

Intervention Type

Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Early reversal of defunctioning ileostomy

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/01/2005

Completion date
31/07/2007

Eligibility

Key inclusion criteria
Patients having defunctioning ileostomy as part of a colorectal procedure, that give informed consent. Patients will be identified through the colorectal meetings, held weekly. Standard treatment will not be affected by involvement in the study. At routine hospital visits the study will be discussed with patients. Those expressing an interest will be given information sheets and contact details.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
Patients that do not give informed consent

Date of first enrolment
31/01/2005

Date of final enrolment
31/07/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Derby Hospitals NHS Foundation Trust
Derby
United Kingdom
DE22 3DT

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
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SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Derby Hospitals NHS Foundation Trust (UK) 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