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Early reversal of defunctioning ileostomy

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

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
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

Study type(s)
Treatment

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Even if subjects are withdrawn prematurely from the study survival data on such subjects will be collated throughout the protocol defined follow-up period for that subject.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(s)
Early reversal of defunctioning ileostomy

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Derby Hospitals NHS Foundation Trust
Derby
United Kingdom
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Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
Derby Hospitals NHS Foundation Trust (UK) NHS R&D Support Funding

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes