

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

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 than 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

Primary study design

Interventional

Study design

Randomised controlled trial

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Even if subjects are withdrawn prematurely from the study survival data on such subjects will be collated throughout the protocol defined follow-up period for that subject.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

DE22 3DT

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