

# Early reversal of defunctioning ileostomy

<b>Submission date</b> 29/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/09/2016	<b>Condition category</b> Surgery	<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**  
Mr J Lund

**Contact details**  
Derby Hospitals NHS Foundation Trust  
Department of Surgery  
University of Nottingham Medical school at Derby  
Derby City General Hospital  
Derby  
United Kingdom  
DE22 3DT  
+44 (0)1332 340131 Ext. 5548  
[jon.lund@nottingham.ac.uk](mailto:jon.lund@nottingham.ac.uk)

## 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 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

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 Even if subjects are withdrawn prematurely from the study survival data on such subjects will be collated throughout the protocol defined follow-up period for that subject.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