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The effect of early oral nutrition and mobilisation on post-operative recovery after major bowel surgery

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 19/07/2017	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Graham Smith

Contact details
University of Leicester
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW
+44 (0)116 258 5291
gs30@le.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RBF 99X22

Study information

Scientific Title
The effect of early oral nutrition and mobilisation on post-operative recovery after major bowel surgery

Study objectives
A patient's recovery after bowel surgery is inhibited by many factors but a common one is post-operative ileus which persists for 3 - 7 days after operation. Typically therefore patients are not fed but are treated with a naso-gastric tube and free drainage with intravenous fluids for 3 - 5 days post-operatively.

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

Health condition(s) or problem(s) studied
Bowel surgery

Interventions
Early oral nutrition and mobilisation on post-operative recovery versus treatment as usual.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

1. Time to passage of first flatus and time to first bowel sounds
2. Visual analogue pain scores will be obtained at rest and during a standard movement at 12-hourly intervals
3. Volume of fluid and/or food taken orally and IV over the duration of the study
4. Fatigue scores will be collected at 12 hourly intervals after operation
5. The time at which patients walk unaided to the bathroom will also be noted

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2000

Completion date
31/07/2002

Eligibility

Key inclusion criteria
Propose to study 50 patients per group.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
100

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/08/2000

Date of final enrolment
31/07/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leicester
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

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.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Trent (UK)

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