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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

- 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. Fatique 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

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/07/2002

Eligibility

Key inclusion criteria

Propose to study 50 patients per group.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre University of Leicester

Leicester United Kingdom LE1 5WW

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

NHS Executive Trent (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration