ISRCTN15405004 https://doi.org/10.1186/ISRCTN15405004

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
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

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

Primary study design
Interventional

Study design
Randomised controlled trial

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. 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

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