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Improving early nutritional intake and functional outcome in postoperative colorectal surgical patients: A randomised clinical trial

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/09/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 12/10/2017	**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
N0503191877

Study information

Scientific Title
Improving early nutritional intake and functional outcome in postoperative colorectal surgical patients: A randomised clinical trial

Study objectives
Not provided at time of registration

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
Surgery: Colorectal

Interventions
1. Intervention group: postoperative prescribed supplementation (ProCal) and standard diet
2. Control group: standard diet only

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Muscle strength at discharge measured using handgrip dynamometry

Key secondary outcome(s))
1. Daily calorie intake
2. Nausea as indicated on a visual analogue scale
3. Days to first flatus
4. Days to first bowel movement
5. Serum albumin levels
6. Length of hospital stay

Completion date
01/10/2007

Eligibility

Key inclusion criteria
All consecutive patients undergoing elective colorectal surgery in the Freeman Hospital, Newcastle upon Tyne

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Any patient with dementia
2. Lactose intolerance
3. Pregnancy
4. Diabetes mellitus
5. Age under 16 years
6. Musculoskeletal conditions preventing accurate use of the handgrip dynamometer
7. Any patient unable to feed orally pre-operatively

Date of first enrolment
01/04/2007

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Freeman Hospital
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Newcastle upon Tyne Hospitals NHS Foundation Trust

Alternative Name(s)
Newcastle upon Tyne Hospitals NHS Trust

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration