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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 12/10/2017	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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NE7 7DN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Muscle strength at discharge measured using handgrip dynamometry

Secondary outcome measures
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

Overall study start date
01/04/2007

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

Age group
Adult

Sex
Both

Target number of participants
46

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

England

United Kingdom

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

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
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

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