

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

Contact name

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Contact details

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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

Primary study design

Interventional

Study design

Randomised controlled trial

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