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'Prehab' or 'Rehab'? Minimising the loss of lean body mass after curative gastrointestinal resection and speeding rehabilitation by exercise and optimised nutrition

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/02/2020	**Condition category** Cancer	[_] 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
Prof M Larvin

Contact details
Southern Derbyshire Acute Hospitals NHS Trust - DCGH
Derby City General Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0077170542

Study information

Scientific Title
'Prehab' or 'Rehab'? Minimising the loss of lean body mass after curative gastrointestinal resection and speeding rehabilitation by exercise and optimised nutrition

Study objectives
To determine if patients scheduled for a curative resection of a gastrointestinal tumour are able to overcome the demands of surgery and metabolic derangements associated with it, more easily, following an optimized nutrition and resistance training programme. The expediated rehabilitation will be judged by body composition, cardiovascular and muscle function and anabolic responses of muscle and whole body protein metabolism. They will be compared with patients receiving only the current best standard care.

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)
Not specified

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Cancer: Gastrointestinal

Interventions
During a routine NHS 76 patients who have been identified as suitable patients at MDT meetings and are agreeable to participating will receive informed consent. Screening investigations will be performed.
Patients will be randomised into two groups; a treatment group and a control group. The treatment group will enter into an eight week fitness regimen consisting of resistance exercises

for twenty minutes three times a week followed by a high energy/ high protein food bar.
The control group will receive advice on nutrition and exercise alone.
There will be two study days for all patients in the study. These will be separated and may be either pre and post intervention of pre and post operative.
On each study day DEXA scanning will be performed and fractional synthetic rate determined in fasted and fed states.
All subjects will attend 7 days after their last acute study. A general examination will be performed with particular attention pain to sites of cannulation and muscle biopsies.
Recent similar studies have attracted large numbers of patients, suggesting that they will be recruitable. Opinions from patients with gastrointestinal cancer have been obtained regarding the study design and information sheets.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Difference in factional synthetic rate as determined by incorporation of leucine and D%-Phenyalanine between treatment group and control group. Quantification of NFf>>B expression, mTOR and p70S6 kinase phosphorylation and protein expression in muscle samples by western analysis.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2005

Completion date
01/10/2006

Eligibility

Key inclusion criteria
During a routine NHS visit 76 patients who have been identified as suitable patients at multidisciplinary team (MDT) meetings and are agreeable to participating will receive informed consent.

Inclusion Criteria: patients with curative colonic cancer.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
76

Key exclusion criteria
1. Metastatic disease
2. Too weak to manage the exercise
3. Unable to give informed consent
4. Patients with insufficient command of the English language
5. Patients taking steroids or betablockers

Date of first enrolment
01/11/2005

Date of final enrolment
01/10/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southern Derbyshire Acute Hospitals NHS Trust - DCGH
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 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
Derby Hospitals NHS Foundation Trust (UK), NHS R&D Support Funding

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