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Pre-operative oral supplementation in colorectal cancer patients

Submission date 03/11/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2012	**Overall study status** Completed	
Last Edited 05/06/2019	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-food-supplement-drinks-people-bowel-cancer-related-weight-loss-posicc

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
101

Study information

Scientific Title
A randomised controlled trial for Pre-operative Oral Supplementation in Colorectal Cancer patients

Acronym
POSiCC

Study objectives
Do oral nutritional supplements and dietary advice compared to dietary advice alone improve clinical outcomes in weight losing colorectal cancer patients?

Are oral supplements and dietary advice cost effective for weight losing colorectal cancer patients compared to dietary advice alone?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee- North West Liverpool East, 15 March 2012, ref: 12/NM/0208

Study design
Pragmatic 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions

The intervention will be in the form of an oral supplement, if patients can tolerate milky drinks Fortisip Compact® (Nutricia Clinical Care) will be used. Patients will be offered a minimum of 250mls of supplement daily (2.4Kcals or 10.1KJ and 0.096g of protein per ml).

If patients cannot tolerate milky drinks they will be offered Fortijuice® as an alternative (Nutricia Clinical Care) and asked to consume 400mls of supplement per day (1.5Kcals or 6.3KJ and 0.04g protein per ml, Fortijuce®).

Patients will be started on the sip feed at the point of diagnosis of a colorectal tumour and when surgery is considered likely to be the treatment option. It is anticipated that the patients will receive the oral supplement for a minimum of two weeks and a maximum of 12 weeks. Patients will be asked to take the supplement up until they are placed on the preoperative carbohydrate drinks prior to surgery.

Patients randomised will either be given dietary advice or oral supplements and dietary advice. The dietary advice will be to increase calories and protein in the diet. Patients will be given a diet sheet on increasing energy and protein in the diet. This advice is appropriate for weight losing patients preoperatively.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fortisip Compact® , Fortijuice®

Primary outcome measure
Number of postoperative chest and surgical site infections after CRC surgery, measured from patient medical records reviewed within 30 days after surgery.

Secondary outcome measures
As of 17/03/2016:
1. Total complications measured up to 30 days postoperatively
2. Anthropometry
3. Body composition and dietary intake
Measured at baseline, 2-3 days preoperatively (where possible) and 7-10 days postoperatively (where possible).

Initial
1. Anthropometry height, weight, body mass index, mid arm circumference (MAC) and skin fold thickness
2. Hand grip strength
3. Co-morbidities
4. 24 hour recalls to assess energy and protein
5. Hospital anxiety and depression score
Measured at baseline, 24 hours preoperatively, 7 days post-operatively and at 3 months

Overall study start date
15/01/2012

Completion date
30/12/2013

Eligibility

Key inclusion criteria
1. Reported weigh loss over the previous 6 months
2. Primary colorectal tumour, eligible for curative surgery
3. Informed consent gained

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
126

Key exclusion criteria
1. Pregnant or enrolled in another trial
2. Pacemaker and any metallic implant will preclude individuals from bioelectrical impedance monitoring
3. Cannot give informed consent

Date of first enrolment
10/10/2012

Date of final enrolment
22/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Room 6.308
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
c/o Dr Karen Shaw
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Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Charity

Funder Name
Macmillan Cancer Care (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes

Results article	results	01/06/2017	Yes	No