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INTERCEPT-C: weight loss and colorectal cancer risk

Submission date	Recruitment status	[_] Prospectively registered
16/10/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/12/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/01/2019	Cancer	

Plain English summary of protocol

Background and study aims
Obesity is a significant health concern and is associated with an increased risk of developing certain types of cancer. However, less is known about how obesity and cancer are linked, and there is little evidence that standard dietary methods of weight loss reduce cancer risk. The aim of this study is to explore the effects of diet-induced weight loss on biomarkers for colorectal cancer risk.

Who can participate?
Men and women, aged 18-60, non-smokers, fluent in English, with body mass index BMI ≥30

What does the study involve?
Participants attend weekly sessions with a Psychologist/Dietitian at University College London where they receive a complete meal replacement plan and support. Participants are asked to have a flexible sigmoidoscopy (a procedure used to see inside the sigmoid colon and rectum) to obtain colon tissue samples from their colon at baseline and follow-up (8 weeks). At the start of the study and after 8 weeks, participants complete a questionnaire on psychological wellbeing and eating habits, have a blood test, and have their body measurements taken (height, weight, body fat, waist and hip circumference).

What are the possible benefits and risks of participating?
If the diet is adhered to, participants will lose weight and they should benefit from the effects of weight loss. In addition, they will be provided with the tools to manage their lifestyle in the longer term to help them successfully maintain the weight loss. Participants will be under the care of a specialist in obesity medicine while on the meal replacement programme. As with all medical procedures there are risks involved, however they are small. The flexible sigmoidoscopy will be carried out by a Consultant Colorectal Surgeon at University College London with a great deal of experience and who is equipped to deal with any issues should they arise. Perforation through the bowel wall or bleeding from biopsy sites are the main risks, but both complications are very rare and only happen in about 1 in every 1,500 examinations. If these occur the Surgeon is experienced in dealing with them. A small proportion of participants may experience anxiety

or mild discomfort during the procedure. Experienced medical professionals will monitor participants throughout. Participants will also be provided with feedback on the flexible sigmoidoscopy results. All participants will have their travel expenses reimbursed.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
July 2013 to July 2014

Who is funding the study?
Cancer Research UK

Who is the main contact?
Dr Rebecca Beeken
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
A14133

Study information

Scientific Title
Intervening to reduce colorectal cancer risk (INTERCEPT-C): a feasibility study to explore the impact of diet-induced weight loss on biomarkers for colorectal cancer

Study objectives
Diet-induced weight loss will be associated with changes in the serum and tissue markers related to colorectal cancer risk.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London, Harrow, 07/03/2013

Study design
Non-randomised single arm exploratory interventional treatment trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

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
Colon cancer, obesity

Interventions
The trialists have designed a weight loss intervention that combines an low calorie diet (LCD~800 calories per day) using the Cambridge Weight Plan products with additional behaviour change techniques from the Shape Up weight management programme developed by the charity Weight Concern. The trialists believe this combined approach will help maximise sustained weight loss and participant well-being. Participants will be on the complete meal replacement programme for 8 weeks this will be followed by 4 weeks in which real food is re-introduced alongside the meal replacement products. Participants will get support and advice on behaviour change on a weekly basis from a Research Psychologist/Dietitian at UCL. Participants will also be weighed at these appointments.

Intervention Type
Behavioural

Primary outcome measure
The following tissue and serum samples will be analysed to measure changes in the levels of cancer-related molecular risk markers:
1. Serum insulin, glucose, total IGFI, IGFBP3, leptin, adiponectin and CRP.

2. Colon epithelial cell mRNA levels (as a measure of gene expression) of insulin/IGF/mTOR and adipokine/inflammatory signaling pathways
3. Colon epithelial cell protein levels of activated (phosphorylated) components of the insulin /IGF/mTOR and inflammatory signalling pathways
Measured at baseline and 8 week follow up.

Secondary outcome measures
1. Weight
2. Waist and hip circumference
3. Body mass index
4. Body fat (estimated using a Tanita Body Fat Scale)
5. Blood pressure
6. General health (General Health Questionnaire; GHQ28,Goldberg & Hillier, 1979)
7. Self-esteem (Rosenberg Self Esteem; RSE Scale, Rosenberg, 1965)
8. Body dissatisfaction (Body Shape Questionnaire; BSQ, Evans & Dolan, 1993)
9. Cognitive restraint over eating, disinhibited eating, and susceptibility to hunger (ThreeFactor Eating Questionnaire; TFEQ, Stunkard & Messick, 1985)
10. Binge eating (Binge Eating Scale; BES, Gormally, Black, Daston, & Rardin, 1982)
11. Depression (Centre for Epidemiologic Studies Depression Scale; CESD, Devins, Orme, Costello, & Binik, 1998)
Measured at baseline and 8 week follow up.

Overall study start date
15/07/2013

Completion date
14/07/2014

Eligibility

Key inclusion criteria
1. Body mass index (BMI) ≥30
2. Aged 18-60
3. Non-smoker
4. Fluent in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. History of major depression
2. History of cardiovascular disease (CVD)
3. Pregnant
4. Taking medication prescribed by a general practitioner over the past month (excluding oral contraceptives)
5. Diabetic
6. Has a disease of the liver, kidney, heart, lung, blood or skin
7. Has had intestinal surgery
8. History of malabsorption
9. Regularly use drugs with anti-inflammatory or antidiabetogenic properties
10. Previous diagnosis of cancer
11. Known food allergies (including lactose intolerance)

Date of first enrolment
15/07/2013

Date of final enrolment
14/07/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation
University College London (UK)

Sponsor details
c/o David Wilson
Research Support Centre
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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK); Ref: A14133

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Cambridge Weight Plan (UK) are providing the meal replacement products for the study

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?
Results article	results	01/11/2017	22/01/2019	Yes	No