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Biomarkers Of Colorectal cancer After Bariatric Surgery

Submission date	Recruitment status
14/11/2013	No longer recruiting
Registration date	**Overall study status**
19/12/2013	Completed
Last Edited	**Condition category**
16/05/2018	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Colorectal (bowel) cancer is a common disease. Obesity is a major health problem and is a known risk factor for bowel cancer. Weight loss surgery is increasingly being used in the management of severe obesity. However, the effect of weight loss surgery on bowel cancer risk is not known. In our previous work we have developed a number of unique biomarkers of bowel cancer risk, which can be measured in small samples (biopsies) taken from the bowel during an examination of the bowel (rigid igmoidoscopy). We have shown that these biomarkers can be detected before the development of bowel cancer and so may be a useful tool to identify those at higher risk of the disease. This study will tell us if obesity and surgically induced weight loss can affect these biomarkers and as a result influence the risk of developing bowel cancer in the future.

Who can participate?
This study aims to recruit about 40 adult men and women who are planned for weight loss surgery. We also aim to recruit 20 healthy volunteers who are not overweight or obese.

What does the study involve?
Blood, urine and stool samples and bowel wall biopsies, as well as body measurements and data on dietary, lifestyle and bowel habits, will be collected from a group of obese patients before and six months after weight loss surgery. We will collect similar samples and data from healthy normal weight individuals to use as a comparison. We can then look for any changes in the expression of these biomarkers, as well as a number of other important cancer-related measures.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. There is a very small risk of causing bleeding and an even smaller risk of causing a perforation (hole or tear) when taking biopsies from the bowel. Steps are taken to minimise these risks.

Where is the study run from?
North Tyneside General Hospital (UK)

When is study starting and how long is it expected to run for?
Participants will be enrolled on the study for a minimum period of one year starting from

November 2013; however, the enrolment period may be extended if necessary. The study is expected to run until the end of April 2016.

Who is funding the study?
Northumbria Healthcare Foundation Trust (UK)

Who is the main contact?
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Impact of obesity surgery on biomarkers of risk of colorectal cancer

Acronym
BOCABS

Study objectives
1. What is the impact of weight loss surgery on biomarkers of colorectal cancer risk?
2. What is the difference, in terms of the impact on the expression of biomarkers of colorectal cancer risk, between the most commonly performed types of weight loss procedures (gastric bypass, sleeve gastrectomy, gastric balloon and gastric band)?
3. What factors, other than weight loss after the weight loss procedures, impact on the biomarkers of CRC risk (such as the effects on insulin pathways, inflammatory pathways and the gut luminal content)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - Newcastle & North Tyneside 2, 02/08/2013, ref: 13/NE/0204

Study design
Single-centre observational study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Obesity; Colorectal cancer; Bariatric surgery

Interventions
BOCABS is an observational study of patients undergoing weight loss surgery.

Pre-operatively participants will have anthropometric measurements. A food portion size estimation interview will be carried out using a photographic food atlas. The participants will be asked to complete a validated food frequency questionnaire, lifestyle questionnaire and a Bristol stool chart diary. Fasting bloods and urine and stool samples will be collected. Rectal biopsies will be obtained using rigid sigmoidoscopy. The participants will be asked to wear an accelerometer (GeneActiv wrist worn physical activity monitor) during awake hours for one week. At the preoperative upper GI endoscopy, as part of routine care, duodenal biopsies will be taken for research purposes. Body composition analysis will be performed using a bioimpedance device (Tanita TBF300MA).

Similar measurements and samples will be taken at the 6-month post-operative follow-up (apart from visceral fat and duodenal biopsies). This will also be the case for the 'normal weight' healthy control group.

Participation will be over a six-month period.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Epithelial cell kinetics of rectal mucosa measured using direct counting of mitotic figures after crypt microdissection; at baseline and repeated at 6 months for those who have bariatric surgery.

Key secondary outcome(s))
1. Epigenetic markers (Wnt signalling pathway) measured using pyrosequencing
2. Gene expression (Wnt signalling pathway) measured using qPCR
3. Mucosal expression of inflammatory markers measured using qPCR and/or immunohistochemistry

All secondary outcomes will be measured at baseline for all participants and repeated at 6 months for those who have bariatric surgery.

Completion date
30/04/2016

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/12/2014:
Intervention group:
Obese adult patients planned for bariatric surgery

Control group:
Healthy adult patients with a normal Body Mass Index (18.5 to 24.9 kg/m2) and a recent (within 1 year) normal endoscopic (colonoscopy or flexible sigmoidoscopy) examination.

Previous inclusion criteria:
Intervention group:
Obese adult patients planned for bariatric surgery

Control group:
Healthy adult patients with a normal Body Mass Index (18.5 to 24.9 kg/m2) and either:
1. A recent (within 6 months) normal colonoscopy undergoing minor anorectal surgery
2. The need for a rigid sigmoidoscopy & completion colonoscopy, as part of routine care

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Pre-bariatric surgery/controls:
1. Age under 16 years old or over 65 years old
2. Previous colorectal resection
3. Previous weight loss surgery
4. Active or previous history of any type of Inflammatory Bowel Disease
5. Familial adenomatous polyposis
6. Lynch syndrome (Amsterdam II criteria)
7. Steroids, except topical, or other immunosuppressive medication
8. Warfarin or other anticoagulation
Added 11/12/2014: 9. Pregnancy

Post-bariatric surgery:
1. Major post-operative complications (defined using Clavien-Dindo classification ≥3)
2. Pregnancy

Exclusion based on rigid sigmoidoscopy findings:
1. Difficulty in performing rigid sigmoidoscopy, either due to anal pathology or other technical difficulty
2. Macroscopically abnormal rectal mucosa
3. Unexpected microscopic abnormality on histological examination of rectal biopsies (e.g. microscopic colitis)

Removed as of 11/12/2014:
Additional exclusion for the 'normal weight' healthy controls:
1. Significant pathology on follow-up colonoscopy

Date of first enrolment
11/11/2013

Date of final enrolment
30/04/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Tyneside General Hospital
Northumbria Healthcare Foundation Trust
Rake Lane
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Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust (UK)

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Northumbria Healthcare Foundation Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes