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The impact of obesity and weight loss on the endometrium

Submission date	Recruitment status	[_] Prospectively registered
10/03/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/04/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/01/2019	Cancer	

Plain English summary of protocol

Background and study aims

Endometrial cancer, or cancer of the lining of the womb, has become the most common cancer of the reproductive tract in British women. Obese women are at increased risk of the disease and are also more likely to die from it. The recent obesity epidemic means that more women than ever before are developing the disease. Endometrial cancer can usually be cured by surgery but for obese or elderly women, surgery may be dangerous. It also renders a woman infertile. There is an urgent need to develop preventative strategies for an increasingly obese female population. Understanding more about the mechanisms linking obesity and endometrial cancer will help the development of these.

Bariatric surgery (reduction of stomach capacity by e.g. gastric banding) results in rapid weight loss: 10-15% excess body weight will be lost in six weeks with resolution of body mass index (BMI) to within the normal/overweight range (BMI 25-30) by 12 months. Non-surgical weight loss management can be effective but produces much slower results. Looking at the changes in the endometrium following weight loss may help us understand what causes endometrial cancer to develop and from there we can then look at what can be done to stop endometrial cancer developing.

Who can participate?

We will recruit around 100-150 morbidly obese (BMI>40) women aged 18 years or more who have been offered bariatric surgery or a non-surgical weight loss programme.

What does the study involve?

Both groups of women will have blood samples and a sample of the lining of the womb (endometrial biopsy) taken at recruitment. The women will then undergo surgery or follow their weight loss programme. All women will attend a follow up appointment 2 and 12 months later when a further blood sample and sample of the lining of the womb will be taken. Women will be asked to report their general health while in the study by filling out a questionnaire. They will also be asked about their quality of life before and after weight loss.

What are the possible benefits and risks of participating?

There will be no direct benefit to many of those taking part, but there should be benefits for future women with endometrial cancer because this study will help us investigate why

endometrial cancer develops. Some patients with underlying endometrial pathology will be identified by taking part in the study, and for these women, further investigations and treatment may be necessary.

Where is the study run from?
Patients will be recruited from the Obesity Clinic at Salford Royal Hospital and followed up at St Marys Hospital in Manchester (UK).

When is study starting and how long is it expected to run for?
The study started April 2012 and is likely to complete April 2016.

Who is funding the study?
The research fellow salaries are funded by Central Manchester University Hospitals NHS Foundation Trust and the project costs are funded by NIHR (UK).

Who is the main contact?
Dr Emma Crosbie
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Contact information

Type(s)
Scientific

Contact name
Dr Emma Crosbie

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 4 - 02.08.13

Study information

Scientific Title
The impact of obesity and weight loss on the endometrium: a prospective cohort study

Study objectives
Obesity and weight loss affect endometrial proliferation

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Lancaster, 23/01/2012, ref: 12/NW/0050

Study design
Prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

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
Endometrial cancer

Interventions
Medical history, height and weight (to calculate BMI) hip and waist measurements a blood sample and an endometrial biopsy will be taken at the baseline clinic visit. At 6 weeks and 9-12 months post-surgery or post-initiation of medical treatment these will all be repeated. A general health questionnaire will be completed at the baseline clinic visit and at 12 months follow up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Ki67 expression by the endometrium (a marker of proliferation) measured at baseline and post weight loss (endometrial biopsy).

Secondary outcome measures
Endometrial markers, physiological markers and changes in menstrual function and mental wellbeing measured at baseline and post weight loss (blood sample and questionnaire).

Overall study start date
01/04/2012

Completion date
01/04/2016

Eligibility

Key inclusion criteria
1. Female aged 18 years or more
2. Undergoing bariatric surgery or commencing medical weight management therapy
3. Written informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
150

Key exclusion criteria
1. Previous hysterectomy
2. Intrauterine device (IUD) or levonorgestrel intrauterine system (LNG-IUS) in situ
3. Previous endometrial ablation
4. Treatment with tamoxifen
5. Pregnancy

Date of first enrolment
01/04/2012

Date of final enrolment
01/04/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Cancer Sciences
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Central Manchester University Hospitals NHS Foundation Trust (CMFT) (UK)

Sponsor details
Oxford Road
Manchester
England
United Kingdom
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Central Manchester University Hospitals NHS Foundation Trust (research fellow salaries)

Alternative Name(s)
MFT

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name
National Institute for Health Research (project costs)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Abstract results	results presented at the annual meeting of the Blair Bell Research Society:	01/11/2015		No	No
Results article	results	01/02/2019		Yes	No