

# The impact of obesity and weight loss on the endometrium

<b>Submission date</b> 10/03/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/04/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/01/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

emma.crosbie@manchester.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Emma Crosbie

### Contact details

Institute of Cancer Sciences

St. Mary's Hospital

Oxford Road

Manchester

United Kingdom

M13 9WL

## 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  
M13 9WL

### 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?
<a href="#">Abstract results</a>	results presented at the annual meeting of the Blair Bell Research Society:	01/11/2015		No	No
<a href="#">Results article</a>	results	01/02/2019		Yes	No