

The impact of obesity and weight loss on the endometrium

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
10/03/2014	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
23/04/2014	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> 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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United Kingdom
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Additional identifiers

Protocol serial number

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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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

United Kingdom

England

Study participating centre

Institute of Cancer Sciences

Manchester

United Kingdom

M13 9WL

Sponsor information

Organisation

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

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

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?
<u>Results article</u>	results	01/02/2019		Yes	No
<u>Abstract results</u>	results presented at the annual meeting of the Blair Bell Research Society:	01/11/2015		No	No
<u>Participant information sheet</u>	Participant information sheet	11/11/2025	11/11/2025	No	Yes