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Progesterone therapy for endometrial cancer prevention in obese women

Submission date 22/04/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/04/2015	**Overall study status** Completed	
Last Edited 29/12/2015	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-giving-hormone-treatment-to-prevent-womb-cancer-in-obese-women-protec1

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18843

Study information

Scientific Title
PROgesterone Therapy for Endometrial Cancer prevention in obese women: an interventional trial

Acronym
PROTEC1

Study objectives
1. To evaluate the efficacy of the Mirena IUS for endometrial protection; including histological impact and the expression of biomarkers of proliferation, apoptosis and other pathways associated with increased risk of endometrial cancer
2. To determine the feasibility, safety and acceptability of using the Mirena IUS for endometrial protection
3. To determine the effect of Mirena IUS insertion on systemic endocrine function and mental and physical wellbeing

Ethics approval required
Old ethics approval format

Ethics approval(s)
15/EE/0063

Study design
Non-randomised; Interventional; Design type: Prevention, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information shee

Health condition(s) or problem(s) studied
Topic: Cancer, Metabolic and endocrine disorders; Subtopic: Gynaecological Cancer, Metabolic and Endocrine (all Subtopics); Disease: Uterus/Endometrium, Metabolic & Endocrine (not diabetes)

Interventions

Women with a BMI >40 who are seen by the Sleep Apnoea Service at Salford Royal Hospital will be asked if they wish to participate in the trial. They will complete a questionnaire, blood samples and biopsies of the lining of the womb taken before and after insertion of a Mirena IUS.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
1. Ki-67

Secondary outcome measures
1. Histopathology
2. Phospho-H3
3. Cleaved Caspase 3, cleaved PARP
4. MAPK signalling molecules and their phosphorylated isoforms
5. P13K-AKT-mTOR signalling molecules and their phosphorylated isoforms
6. PTEN and AMPK, P53
7. Strathmin, cyclin A, c-myc
8. Oestrogen, progesterone, LH, FSH, insulin, adiponectin and leptin receptors
9. IGF-1IR, IGF2, EIG121, RALDH2, SFRP-1, SFRP-4, Survivin
10. Endocrine markers including but not limited to:
11. Fasting serum glucose & insulin, HbA1c, IGFBP-1 and C-peptide levels
12. SHBG, oestrogen, progesterone, free androgen index, FSH, LH, testosterone, CRP
13. Leptin, adiponectin
14. Changes in menstrual function, physical and mental wellbeing

Overall study start date
01/05/2015

Completion date
01/11/2016

Eligibility

Key inclusion criteria
1. Women seen in sleep apnoea clinic at Salford Royal Hospital
2. BMI>40
3. Informed consent
4. Aged 18 years or over
5. Not actively trying to lose weight
6. Normal up to date smear
7. Normal endometrial sampling at screening

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
1. Previous hysterectomy
2. LNG-IUS or IUD in situ or in previous 6 months
3. Pregnant or breast feeding, previous endometrial ablation
4. Breast cancer
5. Congenital/acquired uterine anomaly
6. Pelvic inflammatory disease or genital actinomycosis
7. Immunodeficiency
8. Mirena IUS contraindicated
9. Taking systemic progestagens
10. Patient actively trying to lose weight (awaiting bariatric surgery)

Date of first enrolment
01/05/2015

Date of final enrolment
01/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Mary's Hospital Manchester
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Sponsor information

Organisation
National Institute for Health Research

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30-32 Hyde Terrace
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Sponsor type
Government

ROR
https://ror.org/0187kwz08

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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?
HRA research summary			28/06/2023	No	No