

Progesterone therapy for endometrial cancer prevention in obese women

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

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-protect1>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

1. Ki-67

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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

United Kingdom

England

Study participating centre

St Mary's Hospital Manchester

5th Floor (Research)

St. Mary's Hospital

Oxford Road

Manchester

United Kingdom

M13 9WL

Sponsor information

Organisation

National Institute for Health Research

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

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