ISRCTN31662931 https://doi.org/10.1186/ISRCTN31662931

MIrena coil to Reduce Endometrial Neoplastic Abnormalities

Submission date 12/06/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/06/2014	**Overall study status** Ongoing	
Last Edited 11/04/2023	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/trials/a-study-to-work-out-who-might-respond-to-hormone-treatment-for-pre-cancerous-cells-in-the-womb-and-womb-cancer-mirena-study

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
148213

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
16746, IRAS 148213

Study information

Scientific Title
Predicting response to progestins for the treatment of endometrial hyperplasia and endometrioid adenocarcinoma of the endometrium

Acronym
MIRENA

Study objectives
This study aims to determine how microscopic changes in the tissue or blood of patients with endometrial hyperplasia or cancer (endometrial cancer biomarkers) change with progestin treatment and whether certain biomarkers can predict response.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES committee North West Haydock; 07/03/2014; 14/NW/0056

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

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Endometrial hyperplasia and endometrioid adenocarcinoma of the endometrium

Interventions
Current intervention as of 11/04/2023:
A detailed gynaecological history, including parity, menstrual abnormalities, hormonal and contraceptive use will be taken when recruited. Weight, BMI, age and menopausal status will be assessed. Women with grade 1 stage 1a endometrial cancer on imaging or atypical endometrial hyperplasia will be treated with a Mirena coil or oral high-dose progestins where hysterectomy is not recommended by the Gynaecological Oncology Specialist Multidisciplinary Team (due to surgical or anaesthetic risk, for example in a severely obese woman, or for fertility-sparing reasons). Endometrial biopsies and blood samples will be taken at baseline and every 3 months, or more frequently if clinically indicated, during follow up or during surgery, up to a total duration of 60 months. Predictive biomarkers of clinical responsiveness to progestin treatment will be identified using pre-treatment blood and biopsy samples.

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Previous intervention:
A detailed gynaecological history, including parity, menstrual abnormalities, hormonal and contraceptive use will be taken when recruited. Weight, BMI, age and menopausal status will be assessed. Women with grade 1 stage 1a endometrial cancer on imaging or atypical endometrial hyperplasia will be treated with a Mirena coil or oral high dose progestins where hysterectomy is not recommended by the Gynaecological Oncology Specialist Multidisciplinary Team (due to surgical or anaesthetic risk, for example in a severely obese woman, or for fertility-sparing reasons). Endometrial biopsies and blood samples will be taken at baseline and every 3 months, or more frequently if clinically indicated, during follow up or during surgery, up to a total duration of 12 months. Predictive biomarkers of clinical responsiveness to progestin treatment will be identified using pre-treatment blood and biopsy samples.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measure as of 11/04/2023:
Ki-67 and progesterone receptor status; Timepoint(s): At approximately 3-monthly intervals (for up to a total of 60 months)

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Previous primary outcome measure:
Ki-67 and progesterone receptor status; Timepoint(s): At approximately 3 monthly intervals (for up to a total of 12 months)

Secondary outcome measures
Not provided at time of registration

Overall study start date
16/06/2014

Completion date

01/01/2027

Eligibility

Key inclusion criteria
1. Age 18 or more
2. Attending the gynaecological outpatient clinic at St Marys Hospital
3. Biopsy-proven well differentiated endometrioid adenocarcinoma of the endometrium (EC) with no myometrial invasion and/or endometrial hyperplasia (EH)
4. Clinical decision to treat EH or EC with progestins
5. Written, informed consent to take part in the study; Target Gender: Female

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 150; UK Sample Size: 150

Key exclusion criteria
1. Non endometrioid or mixed histology or concerning histological features
2. Myometrial invasion on imaging
3. Progestin therapy contraindicated
4. Unable to sample endometrium pre/post progestin therapy

Date of first enrolment
16/06/2014

Date of final enrolment
14/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

St Mary's Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Sponsor information

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

Sponsor details
St Mary's Hospital
Manchester Royal Infirmary
Oxford Road
Manchester
England
United Kingdom
M13 9WL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

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
Not provided at time of registration

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