

# Mirena coil to Reduce Endometrial Neoplastic Abnormalities

<b>Submission date</b> 12/06/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/06/2014	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/04/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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

### Contact name

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### Contact details

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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?
<a href="#">HRA research summary</a>			28/06/2023	No	No