

Mirena coil to Reduce Endometrial Neoplastic Abnormalities

Submission date 12/06/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/06/2014	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/04/2023	Condition category 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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Additional identifiers

Integrated Research Application System (IRAS)

148213

Protocol serial number

16746

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

Study type(s)

Treatment

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.

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(s)

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)

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)

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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**

United Kingdom

England

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)

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

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