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POET: Prevention Of Endometrial Tumours

Submission date 08/01/2007	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 21/02/2007	**Overall study status** Stopped	
Last Edited 04/06/2015	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-a-way-of-preventing-cancer-of-the-womb-lining

Study website
http://www.poet-trials.co.uk

Contact information

Type(s)
Scientific

Contact name
Prof Shirley V Hodgson

Contact details
Department of Clinical Development Science
Cranmer Terrace
London
United Kingdom
SW17 0RE

Additional identifiers

EudraCT/CTIS number
2006-001815-30

IRAS number

ClinicalTrials.gov number
NCT00566644

Secondary identifying numbers
N/A

Study information

Scientific Title
POET: Prevention Of Endometrial Tumours

Acronym
POET

Study objectives
POET is an interventional, open, randomised controlled trial looking at the efficacy of the Mirena Intrauterine System (IUS) with surveillance, versus surveillance alone, in reducing the development of Atypical Endometrial Hyperplasia (AEH) and carcinoma in women aged 35 to 65 years with Hereditary Non-Polyposis Colorectal Cancer (HNPCC or Lynch Syndrome).

This cohort of women has been selected based on age (35 to 65 years) for inclusion into the study because the risk of Endometrium Cancer (EC) in Lynch syndrome rises from the age of 35 years. This is when surveillance is recommended to start, according to current guidelines. The risk of EC continues to rise post-menopausally so the prophylactic effects of the Mirena IUS could be more significant in this age group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wandsworth REC, 12/04/2005, ref: 05/Q0803/59

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Atypical Endometrial Hyperplasia (AEH) and carcinoma

Interventions
Women will be randomised to receive either Mirena IUS for four years with surveillance (surveillance being annual TransVaginal Sonography [TVS] and Endometrial Biopsies [EB] by

pipelle [or hysteroscopy], to document AEH and carcinoma; pathology confirmed) or surveillance only.

On 17/06/2009 this record was updated to indicate that this trial was closed prematurely due to poor recruitment.

Intervention Type
Device

Primary outcome measure
AEH or EC, during the active follow-up period of the trial

Secondary outcome measures
To address the following questions:
1. What is the age-related incidence of AEH and EC in women with Lynch syndrome?
2. What is the sensitivity and specificity of surveillance with TVS and EB to detect AEH and carcinoma in women with Lynch syndrome?
3. What is the premalignant pathway to carcinoma in women with Lynch syndrome?
4. Does the Mirena IUS reduce the rate of therapeutic hysterectomy for AEH or cancer in women with Lynch syndrome?
5. Are there psychological benefits or adverse effects from the use of the Mirena IUS?
6. What is the satisfaction and compliance with screening?
7. What is the extent of adverse effects of surveillance and use of the Mirena IUS? (subsequent investigation of abnormalities detected on surveillance or side-effects of the Mirena)
8. In the longer term, with separate funding, we will determine the molecular changes associated with pre-malignant changes in the endometrium in women with Lynch syndrome, and possibly the utility of tests on cervical mucus samples to diagnose endometrial neoplasia.

Overall study start date
15/01/2007

Completion date
31/01/2013

Reason abandoned (if study stopped)
Lack of participants

Eligibility

Key inclusion criteria
Women aged 35 to 65 years are eligible if:
1. Proven to carry a pathogenic germline mutation in a DNA mismatch repair gene causing Lynch syndrome (usually MSH2, MLH1, MSH6)
2. Women:
a. from a family fulfilling the Amsterdam or the modified Amsterdam criteria for Lynch syndrome (three relatives with an Lynch syndrome-related cancer (colorectal, small bowel, endometrial, ovarian, urothelial or hepatobiliary), one the first-degree relative of the other two, two generations affected, and one diagnosis before the age of 50 years)

AND

b. who themselves have had colorectal cancer, a large, villous or severely dysplastic colorectal adenoma before the age of 40 years, or small bowel, hepatobiliary, or urothelial cancer, and where abnormal immunohistochemistry staining for Lynch syndrome proteins in the tumour has been demonstrated in an affected family member.

The aim is to randomise 220 women within 18 months of opening the trial. However, randomising as many as 800 women could be justified in order to evaluate the effect of Mirena separately pre- and post-menopause.

3. Risk equivalent
A patient may be randomised in the POET trial if it can be proved that she is a carrier. For example, this could be due to the woman being an obligate carrier in a family meeting the Amsterdam Criteria and including other evidence of a mis-match repair defect.

Having a risk equivalent entry point will also allow for someone who was only a second degree relative of an affected family member, but who herself had had bowel cancer at age 35, for instance, to be eligible in the trial.

Eligibility will be confirmed in writing by Prof. Hodgson, Dr Sheridan or Dr Murday and a copy of the email/letter will be kept with the patients notes for monitoring purposes.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
220

Key exclusion criteria
1. Women without an intact uterus (or who are planning a prophylactic hysterectomy)
2. Known or suspected pregnancy
3. Women trying to become pregnant in the next three years
4. Infected abortion during the three months before Mirena insertion is planned
5. Concomitant use of intrauterine devices
6. History of, or active, genital malignancy or breast carcinoma or other oestrogen dependent tumours
7. Any kind of active malignancy
8. Currently on therapy for cancer
9. Pelvic inflammatory disease (PID) during previous 6 months (before the Mirena IUS insertion) or recurrent PID
10. Clinically significant submucous myomas requiring treatment. Small subserous or intramural myomas, clinically assessed as insignificant, are acceptable
11. Any known hypersensitivity to the constituents of the Mirena IUS

12. An unresolved abnormal cervical smear
13. Trophoblastic disease while hCG levels remain elevated
14. Any clinically significant condition or laboratory result that might, in the opinion of the investigator, compromise patient safety, interfere with the evaluations or prevent the completion of the trial
15. Outside the age-range for the study
16. Current or previous severe arterial disease (Stroke, M1) or severe liver disease

Date of first enrolment
11/07/2007

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St George's, University of London
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
St George's, University of London & Queen Mary and Westfield College, University of London (UK)

Sponsor details
R & D, Floor 3
Rutland House
42-46 New Road
Whitechapel
London
England
United Kingdom
E1 2AX

Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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