# **POET: Prevention Of Endometrial Tumours**

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

## 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 ORE

# 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)

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 ORE

# 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