

# Preventing recurrence of endometriosis by means of long acting progestogen therapy

<b>Submission date</b> 20/03/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/03/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/09/2024	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Endometriosis is a common condition where cells similar to those within the lining of the womb are found in abnormal locations elsewhere in the body, commonly within the pelvis. Like the lining of the womb itself, these cells go through a phase of growth followed by breakdown and bleeding. This internal bleeding within the pelvis causes inflammation, the formation of scar tissue (adhesions) and is associated with pain. Endometriosis occurs in 6-10% of women of reproductive age. The condition is painful and can have a serious impact on their lives. Many will need surgery to remove areas of endometriosis in order to relieve pain. However, symptoms of endometriosis tend to return and women need to go through repeated surgery including removal of their womb and ovaries. Previous research has suggested that medicines containing female hormones (progestogens) can reduce the chances of symptoms returning. Treatments in this class are contraceptives and include a coil, injections, or the pill. However, these studies were done with small numbers of participants and were unable to provide definitive results. The aim of this study is to compare the effectiveness of these different treatment options in women undergoing surgery for endometriosis.

### Who can participate?

Women aged 16-45 with no immediate plans to conceive who are undergoing surgery for endometriosis

### What does the study involve?

Participants are randomly allocated to take either long-acting progestogens (either as three monthly injections or as a coil, which is inserted into the womb where it remains for five years), or long-term treatment with the oral contraceptive pill.

### What are the possible benefits and risks of participating?

The study will provide information on which treatment is the most effective in terms of symptom relief, side-effects, acceptability and costs. This information will be vital in terms of future clinical decision making in an area of uncertainty.

### Where is the study run from?

University of Aberdeen (UK) and 35 other centres, BCTU is the coordinating centre

When is the study starting and how long is it expected to run for?  
March 2014 to June 2021

Who is funding the study?  
National Institute for Health Research (UK)

Who is the main contact?  
Prof. Kevin Cooper  
kevin.cooper@nhs.net

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Kevin Cooper

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## Additional identifiers

**EudraCT/CTIS number**  
2013-001984-21

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
16166

## Study information

**Scientific Title**  
PRE-EMPT: Preventing Recurrence of Endometriosis by Means of long acting Progestogen Therapy

**Acronym**  
PRE-EMPT

## **Study objectives**

Current study hypothesis as of 17/07/2017:

A large randomised controlled trial in which women undergoing surgery for endometriosis will be randomly allocated to take long acting progestogens (either as three monthly injections or as a coil, which is inserted into the womb where it remains for five years), or long term treatment with the oral contraceptive pill.

Previous study hypothesis:

A large randomised controlled trial in which women undergoing surgery for endometriosis will be randomly allocated to take long acting progestogens (either as three monthly injections or as a coil, which is inserted into the womb where it remains for five years), or long term treatment with the oral contraceptive pill, or no treatment.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

East of Scotland Research Ethics Service (EoSRES), 12/09/2013, ref: 14/ES/1004

## **Study design**

Randomised; Interventional; Design type: Treatment

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

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

## **Health condition(s) or problem(s) studied**

Topic: Reproductive Health; Subtopic: Reproductive Health and Childbirth (all Subtopics);  
Disease: Reproductive Health & Childbirth

## **Interventions**

Combined oral contraceptive pill, if an option and allocated by randomisation:

Initial prescription dispensed by gynaecologist, before discharge, or else as soon as possible by GP or at family planning clinic. Subsequent prescriptions by GP or at family planning clinic.

DMPA injection, if an option and allocated by randomisation:

Initial injection by gynaecologist, before discharge, or else as soon as possible by GP or family planning clinic. Subsequent 3 monthly injections by GP or at family planning clinic.

LNG-IUS insertion, if an option and allocated by randomisation:  
Initial insertion by gynaecologist, either during laparoscopy or before discharge, or else as soon as possible by GP or at family planning clinic.

#### Laparoscopy

All participants will have a laparoscopy to diagnose endometriosis and for excision/ablation or endometrial lesions if found. These will be either in a single procedure or two procedures, depending on clinician's decision.

#### Intervention Type

Other

#### Phase

Phase IV

#### Primary outcome measure

Recurrence of symptoms, evaluated by the pain domain of the EHP-30 questionnaire

#### Secondary outcome measures

1. All other symptom and quality of life (QoL) domains of the EHP-30
2. Non-menstrual pelvic pain

#### Overall study start date

14/03/2014

#### Completion date

30/06/2021

## Eligibility

#### Key inclusion criteria

1. Women aged 16-45
2. No immediate plans to conceive
3. Are scheduled to have laparoscopic conservative surgery, or a diagnostic laparoscopy with concurrent surgery if endometriosis is found, for pelvic pain associated with endometriosis

(Pilot phase) willing to be randomised to at least one long-acting progestogen (LNG-IUS/DMPA) and COCP

#### Participant type(s)

Patient

#### Age group

Mixed

#### Lower age limit

16 Years

#### Upper age limit

45 Years

**Sex**

Female

**Target number of participants**

400

**Total final enrolment**

403

**Key exclusion criteria**

Any women, who at the point of randomisation have any of the following, are not eligible for the trial:

1. Current infertility (trying for a baby, receiving or contemplating fertility treatment)
2. Deep infiltrating endometriosis, involving the bowel or rectovaginal septum, and requiring complex surgery, whether pre-planned or identified at laparoscopy
3. Contraindications to the use of hormonal treatment with oestrogen or progestogens
4. Suspicion of malignancy

**Date of first enrolment**

01/05/2014

**Date of final enrolment**

28/02/2019

**Locations****Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

University of Aberdeen

Aberdeen

United Kingdom

AB25 2ZD

**Study participating centre**

35 centres

United Kingdom

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**Sponsor information**

**Organisation**

NHS Grampian (UK)

**Sponsor details**

Foresterhill House  
Ashgrove Road West  
Aberdeen  
Scotland  
United Kingdom  
AB25 2ZB

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/00ma0mg56>

**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**

Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**

30/06/2022

**Individual participant data (IPD) sharing plan**

The current data sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>	Internal pilot focus group results	11/03/2017		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Results article</a>		15/05/2024	21/05/2024	Yes	No
<a href="#">Results article</a>		01/09/2024	12/09/2024	Yes	No