ISRCTN97865475 https://doi.org/10.1186/ISRCTN97865475

Preventing recurrence of endometriosis by means of long acting protestogen therapy

Submission date
20/03/2014

Recruitment status
No longer recruiting

Registration date
20/03/2014

Overall study status
Completed

Last Edited
12/09/2024

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 is 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

Contact details
University of Aberdeen
Polwarth Building
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD
+44 (0)1224 554800
kevin.cooper@nhs.net

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 is 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 is 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
-

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?
Other publications	Internal pilot focus group results	11/03/2017		Yes	No
HRA research summary			28/06/2023	No	No
Results article		15/05/2024	21/05/2024	Yes	No
Results article		01/09/2024	12/09/2024	Yes	No