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Post-operative levonorgestrel-releasing intra uterine system (IUS) treatment after conservative surgery for symptomatic endometriosis stage I to IV to reduce pelvic pain symptoms

Submission date	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/10/2017	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0256159399

Study information

Scientific Title
Post-operative levonorgestrel-releasing intra uterine system (IUS) treatment after conservative surgery for symptomatic endometriosis stage I to IV to reduce pelvic pain symptoms

Study objectives
Can we reduce the recurrence of pelvic pain after conservative surgical treatment by inserting the IUS at the time of surgery?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Pelvic pain

Interventions
Randomised Clinical Trial

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Reduction in severity of dysmenorrhoea, pelvic pain and deep dyspareunia as assessed by multidimensional analogue questionnaire between the group treated with levonogestrel-IUS and controls

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2002

Completion date
31/12/2004

Eligibility

Key inclusion criteria
40 patients and 40 controls

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
80

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/01/2002

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Department Of Obstetrics and Gynaecology
London
United Kingdom
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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United Kingdom
SW1A 2NL
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Royal Free Hampstead NHS Trust (UK) NHS R&D Support Funding

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