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Effectiveness and Cost-effectiveness of Levonorgestrel containing Intrauterine system in Primary care against Standard treatment for menorrhagia

Submission date
10/06/2004

Recruitment status
No longer recruiting

Registration date
11/06/2004

Overall study status
Completed

Last Edited
06/11/2023

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
HTA 02/06/02

Study information

Scientific Title
Effectiveness and Cost-effectiveness of Levonorgestrel containing Intrauterine system in Primary care against Standard treatment for menorrhagia: a randomised controlled trial

Acronym
ECLIPSE

Study objectives
Menorrhagia is a very common problem affecting women's lives. Attendant demand on time and resources in primary and secondary care is considerable. However it is unclear which treatment options are the most effective and the most acceptable to women, particularly in the long term, and experience of care varies widely. Currently 1 in 5 women in the UK have a hysterectomy, half of whom present with heavy periods. This trial will assess the effectiveness, cost effectiveness and acceptability of using the levonorgestrel IUS (Mirena coil) compared to standard medical treatment for women with menorrhagia presenting in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Research Ethics Committee, 18/08/2004, ref: 04/MRE06/7. The latest approval for amendments was given on 25/07/2008.

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Menorrhagia

Interventions
Levonorgestrel-releasing intrauterine systems compared with standard medical treatment, based on the Royal College of Obstetricians and Gynaecologists (RCOG) guidelines

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Levonorgestrel

Primary outcome(s)
Added as of 30/01/2009:
The Shaw Menorrhagia Questionnaire

All primary and secondary outcomes will be assessed at baseline, 6 months, 1, 2 and 5 years with a possibility of 10 years.

Key secondary outcome(s))
Added as of 30/01/2009:
1. SF-36® Health Survey
2. Sexual Activity Questionnaire
3. Euroqol EQ-5D

All primary and secondary outcomes will be assessed at baseline, 6 months, 1, 2 and 5 years with a possibility of 10 years.

Completion date
31/12/2014

Eligibility

Key inclusion criteria
Women between the ages of 25-50 presenting to General Practitioners with menorrhagia, who are not intending to become pregnant in the next 5 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit
50 years

Sex
Female

Total final enrolment
571

Key exclusion criteria
1. Taking HRT
2. Patients with any contraindications to an IUS, with or without Levonorgestrel
3. Patients with contraindications to medical therapy
4. Women with abdominally palpable enlarged fibroid uteri (10-12 Weeks size)
5. Women to whom the contraceptive effect of LNG-IUS would be unacceptable.
6. Women with symptoms suggestive of other pathology (irregular bleeding, intermenstrual bleeding, postcoital bleeding)
7. Women with risk factors for endometrial cancer (tamoxifen treatment, unopposed ostrogen treatments)

Date of first enrolment
01/11/2004

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birmingham Women's Hospital
Birmingham
United Kingdom
B15 2TG

Sponsor information

Organisation
University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/01/2013		Yes	No
Results article	results	01/10/2015		Yes	No
Results article		14/11/2022	15/11/2022	Yes	No
Other publications	10-year observational follow-up study	01/10/2023	06/11/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes