

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

☒ Prospectively registered

☐ Protocol

Registration date

11/06/2004

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

06/11/2023

Condition category

Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.eclipse.bham.ac.uk/>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Patient information can be found at: http://www.eclipse.bham.ac.uk/documents/Eclipse_PIS_v1.1_dated_21.07.08.pdf

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/11/2004

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

Age group

Adult

Lower age limit

25 Years

Upper age limit

50 Years

Sex

Female

Target number of participants

570

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 oestrogen treatments)

Date of first enrolment

01/11/2004

Date of final enrolment

31/12/2014

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Birmingham Women's Hospital

Birmingham

United Kingdom

B15 2TG

Sponsor information

Organisation

University of Birmingham (UK)

Sponsor details

Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type

University/education

Website

<http://www.bham.ac.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, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

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

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

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