

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

<b>Submission date</b> 10/06/2004	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/06/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/11/2023	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

**Protocol serial number**

## 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 oestrogen 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?
<a href="#">Results article</a>	results	10/01/2013		Yes	No
<a href="#">Results article</a>	results	01/10/2015		Yes	No
<a href="#">Results article</a>		14/11/2022	15/11/2022	Yes	No
<a href="#">Other publications</a>	10-year observational follow-up study	01/10/2023	06/11/2023	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes