

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 11/06/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/11/2023	Condition category 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

Contact name
Prof Janesh Gupta

Contact details
Academic Department of Obstetrics and Gynaecology
Birmingham Women's Hospital
Metchley Park Road
Edgbaston
Birmingham
United Kingdom
B15 2TG
+44 (0)121 607 4751
j.k.gupta@bham.ac.uk

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 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?
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