ISRCTN58283041 https://doi.org/10.1186/ISRCTN58283041

Suppression of breakthrough bleeding in levonorgestrel intrauterine system (Mirena system) users

Submission date	Recruitment status
08/11/2006	No longer recruiting
Registration date	**Overall study status**
28/12/2006	Completed
Last Edited	**Condition category**
16/11/2009	Urological and Genital Diseases

[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NIH-1

Study information

Scientific Title

Acronym
MUSE

Study objectives
1. Acceptibility study: development of questionnaire to assess acceptability of bleeding frequency and impact of proposing treatment in breakthrough bleeding.
2. Evaluate intervention strategy for suppression of breakthrough bleeding.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Lothian Research Ethics Committee on the 11th February 2003 (ref: REC/2002/6/39).

Study design
Randomised, double blind, placebo controlled parallel group study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Breakthrough bleeding

Interventions
Administration of CDB-2914 for three consecutive days, for the first three months after LNG-IUS insertion.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Suppression of breakthrough bleeding in new users of LNG-IUS users.
2. Acceptability of breakthrough bleeding frequency.

Secondary outcome measures
Underlying mechanism of breakthrough bleeding.

Overall study start date
01/01/2005

Completion date
01/08/2007

Eligibility

Key inclusion criteria
1. Healthy female volunteers aged between 19 to 48 years
2. Requesting and receiving a LevoNorGestrel IntraUterine System (LNG-IUS) for contraception
3. Must have menstrual cycle of 17 to 42 days, lasting not longer than ten days
4. Not currently using any form of hormonal treatment

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
150

Key exclusion criteria
1. Is less than three months postpartum
2. Is less than one month post-lactation
3. Has been sterilised
4. Abnormal laboratory test finding clinically significant at screening or insertion
5. Currently participating in another study
6. History of cancer in the five years previously
7. History of significant medical disease
8. History of significant psychatric illness
9. Is currently on corticosteroid therapy
10. Unwilling or unsuitable for assessment and follow up
11. History of drug/alcohol abuse in past year
12. Found to have significant gynaecological disorder
13. History of abnormal vaginal bleeding
14. Has coagulopathy or on anticoagulation
15. Allergy to ingredients

Date of first enrolment
01/01/2005

Date of final enrolment
01/08/2007

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
47 Little France Crescent
Edinburgh
United Kingdom
EH16 4TJ

Sponsor information

Organisation
National Institute of Child Health and Development (NICHD) (USA)

Sponsor details
National Institutes of Health
9000 Rockville Pike
Maryland
Bethesda
United States of America
20892

Sponsor type
Government

Website
http://www.nih.gov

ROR
https://ror.org/04byxyr05

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health (USA) - US National Institute of Child Health and Development (NICHD-USA)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2010		Yes	No