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

Submission date Recruitment status Prospectively registered 08/11/2006 No longer recruiting [] Protocol Statistical analysis plan Registration date Overall study status 28/12/2006 Completed [X] Results [] Individual participant data Last Edited Condition category 16/11/2009 **Urological and Genital Diseases**

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

Underlying mechanism of breakthrough bleeding.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

Scotland

Study participating centre

47 Little France Crescent

Edinburgh United Kingdom EH16 4TJ

Sponsor information

Organisation

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

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

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