

The effect of a single dose of mifepristone given midcycle on the pattern of menstrual bleeding

Submission date

22/05/2003

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

22/05/2003

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

07/09/2009

Condition category

Urological and Genital Diseases

☐ Individual participant data

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

G9523250

Study information

Scientific Title

Study objectives

To investigate the effects of a single dose of mifepristone on the length of the menstrual cycle and the pattern of menstrual bleeding.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Other

Health condition(s) or problem(s) studied

Obstetrics and gynaecology: Menstrual bleeding

Interventions

10 mg, 25 mg, 200 mg mifepristone or placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Mifepristone

Primary outcome(s)

The length of the menstrual cycle and the pattern of menstrual bleeding.

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/09/2003

Eligibility

Key inclusion criteria

1. Female volunteer aged 18-40 years inclusive
2. Prepared to use barrier methods for the duration of the study, already have an Intra-Uterine Device (IUD) in-situ, previously sterilised (subject or partner), or not requiring contraception
3. Regular menstrual cycles of between 25 to 35 days with no greater than three days variation in the past three months
4. Willing to provide written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Lower age limit

18 Years

Upper age limit

40 Years

Sex

Female

Key exclusion criteria

1. Those who have used any type of hormonal contraception within three months of starting the trial
2. Clinically relevant abnormal findings during the physical/gynaecological examination
3. Those who have breastfed in the past three months
4. Current treatment with corticosteroids
5. Treatment with an investigational drug within one month of inclusion
6. Long term use of any prescription drugs for a significant medical condition
7. Chronic alcoholism, drug abuse or any other condition associated with poor patient compliance
8. Undiagnosed vaginal bleeding
9. Other significant disease e.g. cardiovascular, renal or liver disease or malignancy, sufficient to interfere with the evaluation of the study

Date of first enrolment

01/12/2001

Date of final enrolment

30/09/2003

Locations**Countries of recruitment**

United Kingdom

Scotland

Study participating centre
Department of Obstetrics and Gynaecology
Edinburgh
United Kingdom
EH16 4SB

Sponsor information

Organisation
University of Edinburgh (UK)

ROR
<https://ror.org/01nrxf90>

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/10/2006		Yes	No