

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

<b>Submission date</b> 22/05/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/05/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/09/2009	<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

### Contact name

Prof DT Baird

### Contact details

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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

### Study design

Randomised controlled trial

### Primary study design

Interventional

### 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?
<a href="#">Results article</a>	results	01/10/2006		Yes	No