

# The effect of daily low dose mifepristone on the endometrium - study over four consecutive cycles

<b>Submission date</b> 25/10/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/10/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/09/2007	<b>Condition category</b> Pregnancy and Childbirth	<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 assess the effect of daily low dose mifepristone (2 mg or 5 mg) on the ovarian cycle, menstrual bleeding patterns, ovarian follicular growth and the endometrium over a four month period

### 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)

Not Specified

### Health condition(s) or problem(s) studied

Obstetrics and gynaecology

### Interventions

Low dose mifepristone versus placebo.

Follow-up: all participants will attend for screening (on or before day 1 of the control cycle) and then on day 12 of the control cycle for endometrial biopsy and ultrasound scan. They will attend for study visits following 30, 60, 90 and 120 days of treatment, and also 30 days post-treatment.

### Intervention Type

Drug

### Phase

Not Specified

### Drug/device/biological/vaccine name(s)

mifepristone

### Primary outcome(s)

Assessment include menstrual blood loss, urinary oestrogen and progesterone, ultrasound scanning, endometrial evaluation and clinical chemistry and haematology variables. Paired t-tests Wilcoxon signed rank and ANalysis Of VAriance (ANOVA) will be used as appropriate

### Key secondary outcome(s)

Not provided at time of registration

### Completion date

01/05/1997

## Eligibility

### Key inclusion criteria

1. Women aged 18-40 inclusive
2. Regular menstrual cycles
3. Willing and able to take part in the study
4. Prepared to use barrier contraception for the duration of the study
5. Those who are sterilised or whose partner is sterilised
6. Negative serum alpha HCG test before commencing the study (pregnancy test)
7. Written informed consent

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Upper age limit

40 years

### Sex

Female

### Key exclusion criteria

1. Those who have used hormonal contraception in the past three months, or depot hormones within six months of entering the trial
2. Those who have breastfed in the past three months
3. Those who have had an IUD in situ in the past three months
4. Long term use of any prescription drugs for a significant medical condition
5. History of cervical surgery which may make endometrial biopsy impossible
6. Pregnancy
7. Vaginal bleeding of unknown aetiology or intermenstrual bleeding

### Date of first enrolment

01/03/1996

### Date of final enrolment

01/05/1997

## Locations

### Countries of recruitment

United Kingdom

Scotland

**Study participating centre**

**Department of Obstetrics and Gynaecology, Centre for Reproductive Biology**

Edinburgh

United Kingdom

EH16 4SB

## Sponsor information

**Organisation**

Medical Research Council (MRC) (UK)

## Funder(s)

**Funder type**

Research council

**Funder Name**

Medical Research Council (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	01/05/2004		Yes	No