

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

Submission date 25/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/10/2000	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/09/2007	Condition category 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/1996

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

40 Years

Sex

Female

Target number of participants

40

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

Scotland

United Kingdom

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)

Sponsor details

20 Park Crescent

London

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W1B 1AL

+44 (0)20 7636 5422

clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.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, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	01/05/2004		Yes	No