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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2000	**Overall study status** Completed	
Last Edited 12/09/2007	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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, 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	01/05/2004		Yes	No