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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
Registration date 22/05/2003	**Overall study status** Completed
Last Edited 07/09/2009	**Condition category** Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Department of Obstetrics and Gynaecology
Centre for Reproductive Biology
University of Edinburgh
49 Little France Crescent
Old Dalkeith Road
Edinburgh
United Kingdom
EH16 4SB
+44 (0)131 242 6200
dtbaird@ed.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Other

Participant information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2001

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

Age group
Not Specified

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
400

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
Scotland

United Kingdom

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

Sponsor information

Organisation
University of Edinburgh (UK)

Sponsor details
Old College
South Bridge
Edinburgh
Scotland
United Kingdom
EH8 9YL
+44 (0)131 650 1000
communications.office@ed.ac.uk

Sponsor type
University/education

Website
http://www.ed.ac.uk/

ROR
https://ror.org/01nrxwf90

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, 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	01/10/2006		Yes	No