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Effect of tailored versus standard use of the combined oral contraceptive on continuation rates at one year

Submission date 12/05/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 31/07/2008	**Overall study status** Completed	
Last Edited 04/04/2013	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MPC 134

Study information

Scientific Title

Study objectives
High rates of unintended pregnancy and abortion in the United Kingdom (UK) are a major public health issue, with over 180,000 abortions each year. The psychological, social and economic costs of unintended pregnancy and abortion exert a heavy toll on service users and the NHS.

Combined oral contraception ('the pill') is a highly effective and safe contraceptive method, but between a third and two thirds of women who do not wish to become pregnant will stop the pill after one year, and one of the chief reasons for this is irregular bleeding. Standard use entails taking the pill daily for 21 days, followed by 7 pill-free days when a monthly withdrawal bleed occurs. Many women wish to have fewer periods and the monthly withdrawal bleed with standard pill use can be prevented by simply leaving out the pill-free days. This seems to cause fewer menstrual symptoms (e.g. headache, breast tenderness, bloating) but more irregular bleeding.

Another option is 'tailored' pill use, where a woman takes the pill daily until bleeding triggers a pill-free interval. The withdrawal bleed that occurs in the pill-free interval seems to discourage further irregular bleeding when the pill is restarted, leading to the desired combination of fewer withdrawal bleeds and less irregular bleeding. If true, tailored use should lead to more women staying on the pill and fewer unintended pregnancies.

We propose a randomised controlled trial (RCT) to find out whether tailored pill use is better than standard pill use by seeing which approach leads to more women staying on the pill for at least a year. We will seek consent from 500 women aged 18 - 45 years attending sexual health services to be randomly allocated to standard or tailored pill use. We will follow them for 12 months and compare results between women taking the pill in the two different ways. The results of the trial will show the best way of taking the pill to help women continue with the pill, minimise unwanted effects and reduce unintended pregnancies in the UK.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Royal Free Hospital and Medical School Research Ethics Committee on the 9th January 2008 (ref: 07/H0720/180).

Study design
A multi-centre, randomised, open, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Not specified

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details provided in the interventions field to request a patient information sheet

Health condition(s) or problem(s) studied
Unintended pregnancy and abortion

Interventions
Standard group:
Microgynon 30 (one pill a day taken orally for 21 days followed by a 7-day pill free interval).

Tailored group:
Microgynon 30, taken orally, continuously (one pill a day) with a 3-day pill free interval triggered by bleeding per vagina for a minimum of 3 consecutive days, which requires the use of sanitary protection on each day. Following the pill free interval, the pill needs to be taken for a minimum of 21 days (3 weeks) before another pill free interval can be taken, triggered by bleeding per vagina for a minimum of 3 consecutive days requiring the use of sanitary protection.

These two groups will take the pill in the allocated way for 12 months. Each woman (regardless of treatment group) will be followed up for 12 months from the time of randomisation (baseline visit); first follow up will be at 3 months after starting on the pill, second follow up will be 6 months after the first follow up visit (at 9 months). Women will be completeing regularly an on-line diary during this time and at 12 months, women will be invited to complete an end of study on-line questionnaire.

Please use the following contact details to request a patient information sheet:
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Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Combined oral contraceptive

Primary outcome measure
Adherence to the pill at 12 months - analysed by end of study questionnaire.

Secondary outcome measures
1. Unbroken use of the pill
2. Time to first break in pill use
3. User satisfaction with contraceptive method at over 12 months
4. User satisfaction with bleeding pattern over 12 months
5. Irregular bleeding over 12 months
6. Other side effects
7. Switching to another pill over 12 months
8. Switching to another method of contraception over 12 months

The secondary outcomes will be assessed by women attending their follow up appointments and by their end of study questionnaire at 12 months.

Overall study start date
01/10/2008

Completion date
31/07/2010

Eligibility

Key inclusion criteria
1. Females greater than or equal to 18 and less than or equal to 45 years of age
2. Requesting combined oral contraceptive (COC) as future or ongoing contraceptive method and for this to be an appropriate choice
3. Willing to be randomised to one of the two groups
4. Willing to follow protocol for 12 months
5. Able to give written consent
6. Access to the internet, has an email address and mobile phone
7. Willing to complete an online diary regularly, i.e. weekly, for up to 12 months after starting the allocated regimen

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
500 - 600

Key exclusion criteria
Any recognised contraindications to COC (UK Medical Eligibility Criteria [UKMEC] points 3 and 4, 2007).

Date of first enrolment
01/10/2008

Date of final enrolment
31/07/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Research Unit
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Sponsor information

Organisation
Camden Primary Care Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.camdenpct.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0906-11154)

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