

ARTICLE/JOURNAL REVIEW

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Statements on funding and competing interests

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Competing interests. None identified.

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Journal Review

Efficacy of a new low-dose oral contraceptive with drospirenone in premenstrual dysphoric disorder. Yonkers KA, Brown C, Pearlstein TB, Foegh M, Sampson-Landers C, Rapkin A. *Obstet Gynecol* 2005; **106**: 492-501

This multicentre, double-blinded, randomised, placebo-controlled trial in the USA aimed to assess the effect of a 24/4 regimen of drospirenone 3 mg and ethinylestradiol 20 µg on symptoms associated with premenstrual dysphoric disorder.

A total of 3496 women were recruited via advertisement and referral, with 450 being blindly randomised to receive either placebo or drospirenone/ethinylestradiol therapy over a 3-month period. A high proportion of initially selected patients either discontinued the study prematurely or did not meet inclusion criteria. Seventy-one patients in the treatment group discontinued the study prematurely with over half complaining of adverse drug events. These included intermenstrual bleeding, headache and nausea.

Response to therapy was measured by daily self-assessment using the Daily Record of Severity of Problems Scale. Data were analysed from the intent-to-treat cohort that included all randomised subjects who took at least one treatment dose. Response to treatment was defined as a 50% reduction in daily symptom score. This occurred in 48% of the active treatment group and 36% of the placebo group (RR 1.7). This was significant at the $p < 0.05$ level but not at $p < 0.01$. This corresponded to a number-needed-to-treat of eight patients.

Although the results suggest that this new low-dose 24/4 regimen of drospirenone 3 mg and ethinylestradiol 20 µg is beneficial in symptom amelioration in premenstrual dysphoric disorder, a comparison was not made with either a standard combined oral contraceptive pill or with the currently marketed 21/7 regimen of drospirenone 3 mg and ethinylestradiol 30 µg (under the trade name of Yasmin®). The study was funded by the pharmaceutical company that supplies the trial drug, and two of the authors were employees of the company.

The cost effectiveness of low-dose drospirenone and ethinylestradiol therapy has yet

to be evaluated and its relative efficacy compared to current treatment will need to be proven before such treatment becomes commonplace in the UK.

Reviewed by **Karen Rose**, MB ChB
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Impact on contraceptive practice of making emergency hormonal contraception available over the counter in Great Britain: repeated cross-sectional surveys. Marston C, Meltzer H, Majeed A. *BMJ* 2005; **331**: 271-275

This paper compares data on contraceptive practice among 16-49-year-old women over 3 years from 2000 to 2002. Approximately 2000 women were surveyed each year as part of the Omnibus multipurpose survey. Women were selected by random sampling of addresses and occupants throughout the UK. Interviewers asked about use of contraceptives and emergency hormonal contraception (EHC).

The most striking change was the source of emergency contraception. The introduction of over-the-counter (OTC) EHC in January 2001 resulted in a marked increase in the proportion of women obtaining EHC from pharmacies (19.7% in 2001 and 32.6% in 2002). There was a corresponding reduction in the proportion supplied from general practice and family planning clinics but little change in supply from emergency departments. Women who bought OTC EHC tended to be older, wealthier and single. Over the same period, the proportion of women using emergency contraception once or more than once a year remained static at approximately 6% and 2%, respectively. There was no significant change in the proportion using reliable contraceptive methods or having unprotected intercourse. The authors conclude that availability of OTC EHC has not led to increased use or encouraged unsafe sex.

The survey did not determine the absolute number of times EHC was used and it excluded women under the age of 16 years. Although the authors attempted to correct for selection bias, they were unable to correct for non-response and recall bias. It was assumed that all EHC obtained from pharmacies was bought, with no mention of free supply under patient group direction. Thus the effect of OTC availability may have been underestimated. The study by Lloyd and Gale in

the October 2005 issue of this journal showed an increase in EHC use in a rural setting since it became available OTC.¹

The impact on numbers of unplanned pregnancies is unknown, but OTC EHC does at least appear to be saving health service time and resources.

Reference

- 1 Lloyd K, Gale E. Provision of emergency hormonal contraception through community pharmacies in a rural area. *J Fam Plann Reprod Health Care* 2005; **31**: 297-300.

Reviewed by **Louise Melvin**, MRCOG, DFFP
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Bleeding patterns after immediate initiation of an oral compared with a vaginal hormonal contraceptive. Westhoff C, Osborne LM, Schafer JE, Morroni C. *Obstet Gynecol* 2005; **106**: 89-96

This study compared 84-day bleeding patterns of 201 women randomly assigned to immediate start ('Quick Start') of a triphasic oral contraceptive pill (25 µg ethinylestradiol) compared with the contraceptive vaginal ring (providing 15 µg ethinylestradiol daily). The women either took their first pill or were fitted with a contraceptive vaginal ring irrespective of where they were in their cycle. They then used barrier contraception for the first 7 days and were asked to record their bleeding patterns on a daily basis. The mean bleeding-spotting days in the 84-day reference period for all women was 19.2 days (17.0 days for ring users and 21.4 days for pill users). As well as confirming the excellent bleeding pattern results found in earlier non-randomised studies for the contraceptive vaginal ring, this study also showed that the 'Quick Start' approach is an acceptable alternative to waiting for menses for both contraceptive methods. This is an important observation as this method is easy to implement, increases initiation and may increase effective use and continuation of contraception. Perhaps we should completely abandon the conventional advice we give to women about starting hormonal contraception 'after your next period'?

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