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Statement on funding and competing interests
Funding. The pilot project was funded by four local primary care trusts through joint commissioning.

Competing interests. None identified.

References
5 Grimes DA, Schulz KF, Cates W Jr, Tyler CW. Local versus general anaesthesia: is there a difference in efficacy, compared with current treatment? Efficacy of a new low-dose oral contraceptive with 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.

This multicentre, double-blind, randomised, placebo-controlled trial in the USA aimed to assess the efficacy 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 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/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.

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