# Oral contraceptives containing drospirenone for premenstrual syndrome (Review)

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[Intervention Review]

# Oral contraceptives containing drospirenone for premenstrual syndrome

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# ABSTRACT

## Background

Premenstrual syndrome (PMS) is a common problem. Premenstrual dysphoric disorder (PMDD) is a severe form of PMS. Combined oral contraceptives (COCs), which have both progestin and estrogen, have been examined for their ability to relieve premenstrual symptoms. A COC containing drospirenone and low estrogen has been approved for treating PMDD in women who choose COCs for contraception.

## Objectives

To review all randomized controlled trials comparing combined oral contraceptives containing drospirenone versus a placebo or another COC for effect on premenstrual symptoms.

#### Search strategy

We searched the computerized databases MEDLINE, POPLINE, CENTRAL, EMBASE, LILACS, PsycINFO, and CINAHL for studies of drospirenone and premenstrual syndrome. We also examined references lists of relevant articles, and wrote to known investigators to find other trials.

#### Selection criteria

We included randomized controlled trials in any language that compared a COC containing drospirenone versus a placebo or another COC for effect on premenstrual symptoms. Primary outcome was the prospective recording of premenstrual symptoms (affective and physical). Adverse events related to COC use were examined.

#### Data collection and analysis

Two review authors independently abstracted data and assessed study quality.

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## Main results

We included five trials with a total of 1600 women. Two placebo-controlled trials of women with PMDD showed less severe premenstrual symptoms after three months with drospirenone (plus ethinyl estradiol (EE) 20g) than with the placebo (WMD -7.83; 95% CI -10.91 to -4.75). The drospirenone group had greater decreases in impairment of productivity (WMD -0.42; 95% CI -0.64 to -0.20), social activities (WMD -0.39; 95% CI -0.62 to -0.15), and relationships (WMD -0.38; 95% CI -0.61 to -0.51). Side effects more common with COC use were nausea, intermenstrual bleeding, and breast pain. Little effect was found on less severe symptoms when comparing drospirenone plus more estrogen to another COC. A six-month study showed fewer symptoms with drospirenone, while a two-year trial found the groups to be similar.

#### Authors' conclusions

Drospirenone plus EE 20  $\mu$ g may help treat premenstrual symptoms in women with PMDD. The placebo also had a large effect. We do not know whether the COC works after three cycles, for women with less severe symptoms, or better than other COCs. Larger and longer trials of higher quality are needed to address these issues. Trials should follow CONSORT reporting guidelines.

# PLAIN LANGUAGE SUMMARY

#### Birth control pills with drospirenone for treating premenstrual symptoms

Premenstrual syndrome (PMS) is a common problem. A severe form of PMS is called premenstrual dysphoric disorder (PMDD). Birth control pills with the hormones progestin and estrogen have been studied for treating such symptoms. A birth control pill with the progestin drospirenone may provide more benefits than other such pills. A drospirenone pill with low estrogen was approved for treating PMDD in women who want to use birth control pills.

We did a computer search for randomized controlled trials in any language that compared a birth control pill with drospirenone and estrogen to a placebo ('dummy') or another birth control pill for effect on premenstrual symptoms. We wrote to researchers to find other trials. We looked at whether the pills reduced symptoms and if side effects were reported. Women recorded their premenstrual symptoms over time.

We found five trials with a total of 1600 women. Two trials compared a sugar pill to a drospirenone pill. All the women had PMDD before the trial. After three months, fewer women on a drospirenone pill with low estrogen had severe premenstrual symptoms than the placebo group did. The drospirenone group had better productivity, social activities, and relationships. Women on the drospirenone pill had more nausea, bleeding between periods, and breast pain. These side effects are common with birth control pills. We found little information on treating less severe premenstrual symptoms. Two trials compared a drospirenone pill with more estrogen to another birth control pill. These women did not all have PMDD. In a six-month trial, fewer of the drospirenone group had premenstrual symptoms. In a two-year study, the groups were similar in symptoms and side effects.

A drospirenone pill with low estrogen seems to help premenstrual symptoms in women with PMDD. The placebo, or dummy pill, also had an effect on symptoms. We do not know if the birth control pill works longer than three cycles, in women with less severe symptoms, or better than other birth control pills. Longer and better studies with more women would help. Trials reports should explain more clearly how the study was carried out.