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# Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis

Prof Anna F Glasier MD [a, b] ... Erin Gainer PhD [j]

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## Summary

### Background

Emergency contraception can prevent unintended pregnancies, but current methods are only effective if used as soon as possible after sexual intercourse and before ovulation. We compared the efficacy and safety of ulipristal acetate with levonorgestrel for emergency contraception.

### Methods

Women with regular menstrual cycles who presented to a participating family planning clinic requesting emergency contraception within 5 days of unprotected sexual

clinic requesting emergency contraception within 5 days of unprotected sexual intercourse were eligible for enrolment in this randomised, multicentre, non-inferiority trial. 2221 women were randomly assigned to receive a single, supervised dose of 30 mg ulipristal acetate (n=1104) or 1Â·5 mg levonorgestrel (n=1117) orally. Allocation was by block randomisation stratified by centre and time from unprotected sexual intercourse to treatment, with allocation concealment by identical opaque boxes labelled with a unique treatment number. Participants were masked to treatment assignment whereas investigators were not. Follow-up was done 5â€“7 days after expected onset of next menses. The primary endpoint was pregnancy rate in women who received emergency contraception within 72 h of unprotected sexual intercourse, with a non-inferiority margin of 1% point difference between groups (limit of 1Â·6 for odds ratio). Analysis was done on the efficacy-evaluable population, which excluded women lost to follow-up, those aged over 35 years, women with unknown follow-up pregnancy status, and those who had re-enrolled in the study. Additionally, we undertook a meta-analysis of our trial and an earlier study to assess the efficacy of ulipristal acetate compared with levonorgestrel. This trial is registered with ClinicalTrials.gov, number NCT00551616.

Findings

In the efficacy-evaluable population, 1696 women received emergency contraception within 72 h of sexual intercourse (ulipristal acetate, n=844; levonorgestrel, n=852). There were 15 pregnancies in the ulipristal acetate group (1Â·8%, 95% CI 1Â·0â€“3Â·0) and 22 in the levonorgestrel group (2Â·6%, 1Â·7â€“3Â·9; odds ratio [OR] 0Â·68, 95% CI 0Â·35â€“1Â·31). In 203 women who received emergency contraception between 72 h and 120 h after sexual intercourse, there were three pregnancies, all of which were in the levonorgestrel group. The most frequent adverse event was headache (ulipristal acetate, 213 events [19Â·3%] in 1104 women; levonorgestrel, 211 events [18Â·9%] in 1117 women). Two serious adverse events were judged possibly related to use of emergency contraception; a case of dizziness in the ulipristal acetate group and a molar pregnancy in the levonorgestrel group. In the meta-analysis (0â€“72 h), there were 22 (1Â·4%) pregnancies in 1617 women in the ulipristal acetate group and 35 (2Â·2%) in 1625 women in the levonorgestrel group (OR 0Â·58, 0Â·33â€“0Â·99; p=0Â·046).

Interpretation

Ulipristal acetate provides women and health-care providers with an effective alternative for emergency contraception that can be used up to 5 days after unprotected sexual intercourse.

Funding

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