

Ulipristal acetate versus levonorgestrel-releasing intrauterine system for heavy menstrual bleeding: the UCON randomised controlled trial and mechanism of action study

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Plain language summary

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What is the problem?

Heavy menstrual bleeding is a common condition that affects the lives of many women. A hormone-releasing coil, fitted inside the womb, is effective in making periods lighter but can make them less regular. A medicine called ulipristal acetate or UPA, taken as a pill, has been shown to reduce rapidly menstrual bleeding in women with large, non-cancerous tumours in the womb, known as fibroids. It was not known whether UPA is effective in women who have heavy periods but do not have fibroids of any significant size.

What did we plan to do?

To find out which treatment was better at controlling heavy periods, 236 women were enrolled in a clinical trial where they received either the hormone coil or UPA. The choice of treatment was made at random by a computer rather than the wishes of researchers or patients, to ensure a fair comparison. Participants completed questionnaires about their symptoms and life quality at intervals up to 1 year.

Twice during the trial, medicines regulatory authorities raised safety concerns about UPA causing liver problems. This resulted in the introduction of regular blood tests. The second time, recruitment to the trial stopped early.

What did we find?

Both treatments improved the symptoms of heavy menstrual bleeding in the majority of women. We found no evidence that UPA was better overall after 1 year of treatment, compared with the hormone coil, although fewer women on UPA continued to have periods. Laboratory studies on samples taken from the lining of the womb showed temporary changes due to UPA, which disappeared after treatment stopped.

What does this mean?

Both treatments improve the symptoms of menstrual bleeding and general wellbeing. Because of safety concerns UPA is not available for all women with heavy menstrual bleeding and new, safer medical treatments are needed.

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