

Oral hormone-blocking drug may help with heavy menstrual bleeding

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About 50 % of women with uterine fibroids—non-cancerous muscle tumors that grow in the uterus—experience heavy menstrual bleeding and other symptoms. Surgery is commonly recommended when these symptoms are severe enough to prompt a woman to seek treatment. The most common surgery used to treat fibroids is removal of the uterus (hysterectomy), though in some cases, removal of the fibroids and repair of the uterus (myomectomy) are performed. Surgery is usually extensive in both cases. Long-acting hormone injections can reduce symptoms such as heavy bleeding in women with fibroids, but side effects can be significant and it can take months for the effects of the medications to wear off.

In a study published in the *New England Journal of Medicine* on January 23, 2020, researchers reported on the effectiveness of a new, rapidly reversible oral pill that was used to reduce heavy menstrual bleeding in women with uterine fibroids. The study, which included a large group of researchers from across the country, was led by Dr. William Schlaff, Chair of the Department of Obstetrics and Gynecology at the Sidney Kimmel Medical College at Thomas Jefferson University.

A total of 790 women, ages 18-51, with heavy bleeding due to fibroids, were enrolled into one of three study arms. One group received the oral pill, elagolix, which reduces the production of the hormones estrogen and progesterone normally produced by a woman's ovaries. When these hormones are suppressed, fibroids usually get smaller and bleeding is reduced. A second group received elagolix plus a low dose of estrogen and progestin ("add-back" therapy) with the hope that the additional hormones would produce the same benefit but reduce the side effects of elagolix used alone (like hot flushes and [bone loss](#)). A third group received identical placebo pills that did not contain elagolix or the "add back" hormones. All of the women enrolled in the two identical trials reported by these researchers were confirmed to

have [uterine fibroids](#) by ultrasound and heavy menstrual bleeding (more than 80mLs of blood loss per cycle) for at least two cycles.

The results showed that 80.4% of the women treated with elagolix alone had a reduction of menstrual bleeding of 50% or more compared to 9.6% of the women in the [placebo group](#). Of those women treated with elagolix plus "add back" therapy, 72% had a reduction of 50% or more. Women treated with elagolix alone had significantly more loss of bone mineral as compared with the women treated with placebo, a known and clinically significant side effect of this class of medications. However, there was no difference between the loss of bone mineral in the group treated with elagolix and "add-back" as compared to those in the placebo group.

For many women with fibroids, severe symptoms like bleeding have a major impact on the quality of life. Surgery and long-acting injectable medications are acceptable treatments for many, but certainly not all [women](#) in this situation.

"The potential value of an oral, easily reversible medication that can be combined with low-dose hormonal "add back" to reduce heavy menstrual bleeding while avoiding problematic symptoms and [side effects](#) could be a major step forward," says Dr. Schlaff.

More information: William D. Schlaff et al, Elagolix for Heavy Menstrual Bleeding in Women with Uterine Fibroids, *New England Journal of Medicine* (2020). [DOI: 10.1056/NEJMoa1904351](https://doi.org/10.1056/NEJMoa1904351)

Provided by Thomas Jefferson University

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