

New European pill works against uterine fibroids

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New research offers hope for the first pill to treat a common problem in young women: fibroids in the uterus. The growths can cause pain, heavy bleeding and fertility problems, and they are the leading cause of hysterectomies.

In two studies, a lower dose of a "morning after" [contraceptive pill](#) stopped the bleeding and shrank the fibroids. It worked as well as shots of a hormone-blocking drug that has unpleasant side effects.

"This is very, very good news. The results are better than we expected," said research leader Dr. Jacques Donnez, of Saint-Luc hospital at the Catholic University of Louvain in Brussels.

He's now testing intermittent long-term use of the [pill](#) to see if that could help [women](#) avoid surgery.

The pill is called Esmya, and it is awaiting marketing approval in Europe. It's a low-dose version of an emergency [birth control pill](#) called ella that came on the market in the United States about a year ago. The new fibroid pill still needs to be tested in the U.S. and won't be available anytime soon.

Fibroids are benign growths in the uterus that are common in women during their childbearing years, mostly in their late 30s and 40s. They usually go away after menopause. Treating fibroids isn't easy. Removing the uterus is the only cure; other treatments include surgery to remove

them or procedures to shrink them with ultrasound or pellets that cut off their blood supply.

With the discovery that the hormone progesterone, as well as estrogen, promotes fibroid growth, scientists have been looking at a class of drugs that can block progesterone's effect on the uterus.

Donnez and his colleagues in several European countries tested Esmya, made by Swiss-based PregLem. Their findings are in Thursday's [New England Journal of Medicine](#).

The two studies involved about 550 [premenopausal women](#) whose fibroid symptoms were serious enough that surgery was planned.

One study compared two doses of Esmya with a [dummy pill](#) for three months. The second tested Esmya against a monthly hormone-blocking shot that shrinks fibroids but causes hot flashes and, with long-term use, can thin bones.. Women in that study got a daily Esmya pill and a dummy shot each month, or a hormone shot and a dummy pill.

In both studies, Esmya stopped the bleeding and shrank fibroids in most patients and worked as well as the shot, but with fewer side effects. Menstrual bleeding was controlled in over 90 percent of the women on Esmya - many within a week, compared to 19 percent of those who took a dummy pill.

At the end of the three months, only about half of the participants went ahead with any kind of fibroid surgery. That allowed the researchers to observe whether improvements lasted over the next six months. They did for many of the Esmya patients, while fibroids started growing after a month in the group that got the hormone shot.

Donnez is now studying whether Esmya could be used long-term, given

periodically if symptoms return, until menopause, when fibroids usually disappear. That means some women, depending on their age, might avoid having surgery at all, said Donnez. He does between six and 10 hysterectomies a week for fibroids.

Despite newer, less invasive alternatives, the rate of hysterectomies remains high, Dr. Elizabeth Stewart, a professor of obstetrics and gynecology at Mayo Clinic, wrote in an editorial in the journal. There's a need for good medical treatments and the new research "represents an important step in that direction."

"It's amazing to me that so many women have uterine fibroids and yet the treatments we have available are pretty few and far between," she said.

The new pill is awaiting final European approval as a treatment before surgery, following a recommendation from the European Medicines Agency in December.

In the U.S. and Canada, Esmya will be developed by Watson Pharmaceuticals Inc., which also sells prescription ella, the contraception pill that helps prevent pregnancy for up to five days after sex.

Watson spokesman Charlie Mayr said the company will soon start a study of the fibroids pill in the United States, but it will be several years before it is ready for government review. It will seek approval in Canada early this year, he said.

Drugmaker PregLem paid for the latest studies. The researchers included company employees; Donnez and others have been on its scientific advisory board.

More information: Journal: <http://www.nejm.org>

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