

## New non-surgical treatment for uterine fibroids can improve quality of life

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A new, effective, non-surgical treatment for uterine fibroids can help women with this condition maintain their fertility, an American scientist told the 26th annual meeting of the European Society of Human Reproduction and Embryology in Rome today (Wednesday). Dr. Alicia Armstrong, Chief, Gynecologic Services, National Institutes of Health (NIH) Programme in Reproductive and Adult Endocrinology, Bethesda, Maryland, said that the outcome of two Phase II clinical trials of ulipristal acetate (UPA) had significant implications for both infertility and general gynaecology patients.

UPA belongs to a relatively new class of drug, the selective progesterone receptor modulators or SPRMs. It is currently used for [emergency contraception](#), and acts by blocking the progesterone receptor and hence ovulation (release of the egg). Recent research has shown that progesterone also plays a role in the development of [uterine fibroids](#), which affect 24 million women in Europe and can lead to a range of symptoms such as abdominal pain and discomfort and heavy and irregular menstrual bleeding. Fibroids are the major indication for hysterectomy in Europe and the US, and they also contribute to infertility by interfering with the ability of the embryo to implant in the womb and causing miscarriage.

"Both the fibroids and the surgical interventions commonly used to treat them can cause significant [fertility problems](#)," said Dr. Armstrong, "and we wanted to see whether fibroids could shrink and surgery could be avoided by using an SPRM."

Results from two Phase II randomised, placebo-controlled, double-blinded studies performed at NIH were pooled and analysed. In the trials, women aged from 25-50 years with symptomatic uterine fibroids were randomised to receive UPA or placebo once a day for three menstrual cycles. The researchers found that, out of the 57 patients who it was possible to evaluate for efficacy, 18 received placebo, 20 10mg of UPA per day and 19 20mg per day. Those taking UPA had reduced total fibroid volume, with those taking the higher dose doing better - 14 (70%) in the 10mg group and 16 (84%) in the 20 mg group. The patients on placebo did significantly less well with only six (33%) showing reduction in fibroid volume.

UPA also reduced bleeding compared with placebo and during the third month of treatment 16 (80%) of patients taking 10mg daily and 18 (95%) on a daily dose of 20mg experienced no menstrual bleeding. At the end of the treatment, patients on the active treatment scored higher in assessment of their quality of life, the severity of their symptoms, their energy levels and mood and their overall concern about the effects of fibroids.

Estradiol levels remained adequate for bone health during treatment in 77%, 100% and 95% of patients in the UPA 10mg and 20mg and placebo groups, respectively, indicating that the action of the ovaries was not impaired, and neither were there any serious side effects. Some women taking UPA had transient increases in liver function tests and a few had the changes in the endometrium that have previously been seen with this class of compounds.

"The results of these trials are convincing and lead us to conclude that UPA is an effective non-invasive treatment for fibroids that can help maintain fertility in women whose only option up to now was to have surgery," said Dr. Lynnette Nieman, Principal Investigator on the NIH trials. "We hope that the results from these trials, along with those from

the Phase III trials currently being conducted by the Swiss company PregLem SA, will allow us to offer this treatment to women who do not want surgery or are unable to have it for medical reasons."

Researchers at the National Institute of Child Health and Human Development are currently carrying out further studies of the molecular action of UPA, Dr Nieman said. "These studies will not only help us understand how the treatment works in women with uterine fibroids, but may give us pointers about which patients might benefit most."

Provided by European Society of Human Reproduction and Embryology

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