

News Summary

O406-4: Women have reduced endometriosis pain with Proellex

An oral drug being tested in women with endometriosis, Proellex, reduces their chronic pelvic pain and their need for painkillers, according to a new study conducted by the drug maker, Repros Therapeutics. The results of the phase 2 clinical trial will be presented Wednesday at The Endocrine Society's 91st Annual Meeting in Washington, D.C.

"Proellex is very effective in relieving pain associated with endometriosis, a condition that affects as many as 4 million women in the United States," said Andre van As, MD, PhD, a study co-author and researcher employed with Repros Therapeutics in The Woodlands, Tex.

Endometriosis involves abnormal growth of tissue outside the endometrium, or uterine lining. Many affected women have severe to debilitating abdominal pain during menstruation, and some women also experience nonmenstrual pelvic pain and painful sexual intercourse. Treatment with oral contraceptives and aspirin or nonsteroidal anti-inflammatory drugs, such as ibuprofen, may relieve pain for some women. Narcotic drugs for relief of pain were used by approximately two thirds of women in the study being reported. Severe cases, however, may require drug injections, surgery to remove endometrial growths or even a hysterectomy with removal of the ovaries.

The van As research team tested the pain-relieving effects of Proellex (CDB-4124) over 4 months in 43 women with endometriosis. These women reported moderately severe or severe pelvic pain and other symptoms of endometriosis, based on the Mean Endometriosis Symptom Severity Scale. The researchers randomly assigned the women to receive, once a day, either a placebo (similar to an inert sugar pill) or Proellex at one of two doses. Fifteen women received placebo, and 14 women each received either 25 or 50 milligrams of Proellex. Neither the participants nor the investigators knew which pill the women received. The three treatment groups had similar average symptom severity scores before treatment, according to the abstract.

Compared with placebo, 4 months of treatment with Proellex significantly lowered individual scores of painful menstruation (called dysmenorrhea), which van As said they expected because the drug causes menstruation to stop in most women. However, Proellex also significantly decreased symptoms associated with nonmenstrual pelvic pain and pain during sexual intercourse ("dyspareunia"), suggesting that this new medication may also have a "disease-modifying effect," van As said. There was no difference in results between the two Proellex doses at any time during the 4 months, he added.

Furthermore, women who received Proellex took fewer painkillers than women who received the placebo. They had a 70.8 percent reduction in use of analgesic drugs versus 45 percent in the placebo group, according to the abstract.

Currently the researchers are studying how long the pain-relieving effects last after stopping Proellex therapy as well as any possible side effects of the drug.

Proellex is in a class of drugs called progesterone receptor modulators. Van As said Proellex prevents the activity of the female sex hormone progesterone. Repros Therapeutics reported that, after further testing, it expects to seek approval of Proellex from the U.S. Food and Drug Administration within the next 2 years for treatment of endometriosis as well as relief of chronic symptoms of uterine fibroids and anemia associated with fibroids.

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