

Annovera birth control vaginal ring effectively prevents unwanted pregnancy, research finds

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A recently approved contraceptive vaginal ring—the first that can be used for an entire year—is a highly effective birth control method, according to clinical trial data that will be presented Tuesday at ENDO 2019, the Endocrine Society's annual meeting in New Orleans, La.

Approved last August by the Food and Drug Administration (FDA), Annovera is a self-inserted system marketed by TherapeuticsMD. The ring is left in place for 21 days and removed for 7 days in each cycle. It provides contraceptive efficacy for up to 13 cycles (1 year) of use. It is designed to release 150 mcg segesterone acetate and 13 mcg ethinyl estradiol per day and has a Pearl index, or failure rate, of 2.98.

"This rate means that only about three <u>unintended pregnancies</u> occur per 100 women in a year compared to a Pearl Index of 80 in couples not using a contraceptive method," said David F. Archer, M.D., an investigator in the Annovera multicenter clinical <u>trials</u> sponsored by the National Institute of Child Health and Human Development, which participated in the new data review.

Segesterone acetate is a new progestin that specifically binds to progesterone receptors. Unlike other combination hormone birth control products, it does not bind to sex hormone-binding globulin and has no estrogenic or androgenic activity. "We wanted to prove whether the segesterone in combination with the low dose of ethinyl estradiol in this



unique vaginal system was adequate at inhibiting ovulation and pregnancy as well as providing good cycle control," Archer said.

The researchers reviewed data from earlier, dose-finding clinical trials that measured how long segesterone stayed in a woman's bloodstream and at what levels. Segesterone acetate serum levels above 105 pmol/L inhibited ovulation in the early trials. Segesterone acetate blood levels decreased only slightly over six months of use in a prior clinical trial with a progestin only ring, and when ethinyl estradiol was added to the ring, segesterone acetate blood levels were unchanged.

"The segesterone acetate release in the current <u>vaginal ring</u> effectively inhibits ovulation, resulting in the high level of contraceptive efficacy for this long-acting, reversible contraceptive," Archer said. He added that the ring's 97 percent success rate is comparable to the most effective birth control methods already on the market, which are at least 95 percent effective.

"Annovera represents a novel, procedure-free and long-acting reversible contraceptive method that can provide contraceptive benefits for up to one year," Archer said.

Provided by The Endocrine Society

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