

New hormonal gel combination shows promise as reversible birth control for men

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Male hormonal contraceptives applied daily to the skin reduce sperm production, finds a new study to be presented at The Endocrine Society's 94th Annual Meeting in Houston.

Very low [sperm](#) counts resulted for about 89 percent of [men](#) using a new combination of hormones, the authors reported. They combined a transdermal (skin) [gel](#) containing the male [hormone testosterone](#) and a gel containing a new synthetic progestin called Nestorone.

"This is the first time that testosterone and Nestorone have been applied to the skin together to deliver adequate amounts of hormones that suppress sperm production," said principal investigator Christine Wang, MD, professor, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center (LA BioMed). "Men can use transdermal gels at home—unlike the usual injections and implants, which must be given in a health care provider's office."

Prior studies of male contraceptives that combined testosterone and progestin used progestin pills, implants or shots, according to Wang. In men, progestin increases the contraceptive effectiveness of testosterone. Both testosterone and progestin work together to turn off production of reproductive hormones controlling the production of sperm, she said. Furthermore, Wang said, unlike other progestins studied as male contraceptives, Nestorone has no androgenic (male hormone) activity. Androgenic activity may cause side effects such as acne and changes in good and bad cholesterol.

In this preliminary study, the investigators randomly assigned 99 healthy men to use one of three unidentified transdermal treatments every day for six months. The assigned treatment was either a gel containing 10 grams of testosterone plus a placebo ("dummy") gel, or the same testosterone gel plus a gel containing either 8 or 12 milligrams (mg) of Nestorone.

Fifty-six men completed at least 20 weeks of treatment and adhered to the study protocol, according to the abstract. Only 23 percent of men who received testosterone alone obtained a sperm concentration less than 1 million sperm per milliliter, "a level that is compatible with very low pregnancy rates," Wang said. For the testosterone-progestin combinations, sperm counts reached that level in 88 to 89 percent of men, depending on the progestin dose.

In addition, complete absence of sperm occurred in significantly more men receiving combined testosterone and progestin than testosterone alone: 78 and 69 percent (8 and 12 mg of progestin, respectively) versus 23 percent for testosterone only.

"The combination of testosterone with Nestorone had few adverse effects," Wang said. "It warrants further study as a male contraceptive."

Nestorone is an investigational new drug being developed by the Population Council, a nonprofit organization in New York City, which supplied this drug for the study. Besins Pharma provided the testosterone gel. Grant funding came from the National Institute of Child Health and Human Development through the Contraceptive Clinical Trials Network. The University of Washington, Seattle, also participated in this study.

Provided by The Endocrine Society

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