

Second potential male birth control pill passes human safety tests

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A new male birth control pill passed tests of safety and tolerability when healthy men used it daily for a month, and it produced hormone responses consistent with effective contraception, according to researchers at two institutions testing the drug. The phase 1 study results was presented Sunday, March 24 at ENDO 2019, the Endocrine Society's annual meeting in New Orleans, La.

The experimental male oral contraceptive is called 11-beta-methyl-19-nortestosterone dodecylcarbonate, or 11-beta-MNTDC. It is a modified testosterone that has the combined actions of a male hormone (androgen) and a progesterone, said the study's co-senior investigator, Christina Wang, M.D., Associate Director, Clinical and Translational Science Institute at Los Angeles Biomed Research Institute (LA BioMed), Torrance, Calif.

"Our results suggest that this pill, which combines two hormonal activities in one, will decrease [sperm production](#) while preserving libido," Wang said.

The study took place in 40 [healthy men](#) at LA BioMed and the University of Washington in Seattle, Wash. Ten [study participants](#) randomly received a placebo capsule, or dummy drug. The other 30 men received 11-beta-MNTDC at one of two doses; 14 men received 200 milligrams, or mg, and 16 got the 400 mg dose. Subjects took the drug or placebo once daily with food for 28 days. The Eunice Kennedy Shriver National Institute of Child Health and Human Development, which is developing 11-beta-MNTDC and other male contraceptives, funded this study.

Among men receiving 11-beta-MNTDC, the average circulating testosterone level dropped as low as in androgen deficiency, but the participants reportedly did not experience any [severe side effects](#). Wang said drug side effects were few, mild and included fatigue, acne or headache in four to six men each. Five men reported mildly decreased sex drive, and two men described mild erectile dysfunction, but sexual activity was not decreased, she said. Furthermore, no participant stopped taking the drug because of side effects, and all passed safety tests.

Effects due to low testosterone were minimal, according to co-senior investigator, Stephanie Page, M.D., Ph.D., Professor of Medicine at the University of Washington School of Medicine, because "11-beta-MNTDC mimics testosterone through the rest of the body but is not concentrated enough in the testes to support sperm production."

Levels of two hormones required for sperm production dropped greatly compared to placebo, the researchers found. The drug effects were reversible after stopping treatment, Wang noted.

Because the drug would take at least three 60 to 90

days to affect sperm production, 28 days of treatment is too short an interval to observe optimal sperm suppression, Wang explained. They plan longer studies, and if the [drug](#) is effective, it will move to larger studies and then testing in sexually active couples.

"Safe, reversible hormonal male contraception should be available in about 10 years," Wang predicted.

Wang said most men are open to using this type of male birth control. She cited a multinational survey of 9,000 men published in the journal *Human Reproduction* in February 2005 that found that 55 percent of men in stable relationships want to try new, hormonal male contraceptive methods if they are reversible.

This experimental contraceptive, 11-Beta-MNTDC, is a "sister compound" to dimethandrolone undecanoate, or DMAU, the first potential male birth control pill to undergo testing by the same research team. Their results were published February 1, 2019 in *The Journal of Clinical Endocrinology and Metabolism*.

"The goal is to find the compound that has the fewest side effects and is the most effective," Page said. "We are developing two oral drugs in parallel in an attempt to move the [contraceptive medicine] field forward."

Provided by The Endocrine Society

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