

# Reversible Male Contraceptive Shows Promise - So Why Stop The Study Early?



By *Kedist Tedla* — November 2, 2016



As it stands now, the burden of contraception rests heavily on a woman's shoulders. Male contraceptive options have been limited to the pull-out method, condoms, and the dreaded "V" word – vasectomy. Understandably, most men shy away from the latter because, well - it involves cutting; and the idea of sharp instruments near the reproductive organs is unfathomable.

Researchers have been working on alternatives to male contraception for quite some time; but while there have been some positive results, no product has made it to the market. According to results of a recent study, injectable male contraception proved to be highly effective and comparable in efficacy to female contraceptives.

The study was done across 7 countries and involved 320 healthy couples with no prior infertility problems. The men were given a combination of two hormones - progestogen and testosterone - which aimed to suppress sperm production to a threshold below fertility requirement ( $<1$  million/mL of semen). Of note, when sperm count is  $<15$  million/mL, a man would be considered essentially infertile. The two drugs were administered as an intramuscular injection, every 8 weeks.

There were three phases to the study. The first 32 weeks (suppression phase) were to decrease sperm production to less than 1 million/mL of semen. During this period, the couple had to use backup, non-hormonal contraception. Next was the efficacy phase of 56 weeks. During this period, no other contraceptives were used and only the study drugs were continued, allowing the effectiveness of the drug to be evaluated with interval pregnancy tests. The third phase involved stopping the study drug to allow recovery of sperm production i.e. recovery of fertility.

The results were as follows:

- **Suppression phase** - 95.9 per 100 participants decreased their sperm count to the desired goal of <1million/mL by 24 weeks.
- **Efficacy phase** - there were 4 pregnancies out of 266 couples who made it to this phase equaling a pregnancy rate of 1.57 per 100.
- **Recovery phase** - 94.8 per 100 participants recovered sperm count to at least 15 million/mL. Five men took longer to recover, while one man failed to recover fertility at 4 years.

The overall failure rate ( a combination of failure to suppress sperm count, spontaneous recovery of sperm count during treatment and failing to regain sperm count) was 7.5%. When compared to the failure rates of other methods: [injectable female contraceptives of \(6%\)](#) [1], [female oral contraceptives \(9%\)](#) [1], and [male condoms \(18%\)](#) [1], the study drug is highly effective.

### **Side effects caused a recommendation to halt the study early**

Adverse effects of the drug were, for the most part (91%) mild, and no worse than those associated with female contraceptives. That is why it is surprising that a peer-review committee recommended that the study be stopped early, citing reports of “mood changes, depression, pain at the injection site, and increased libido”. Furthermore, a disproportionate number of reported mood problems (62/65) came from a single center (Indonesia). Without a placebo group to compare to, the researchers cannot not determine if the reported symptoms outweigh the benefits of the study drug. Women have dealt with side effects since the birth control pill was first approved by the U.S. FDA in 1960.

Despite the issue of mild to moderate adverse effects, more than 75% of the participants were willing to use this type of contraceptive if it were available, but future studies need to clarify the tolerability issue before that becomes a reality.

This type of contraception is not without caveats. It strongly favors couples that are in a long-term relationship, as it takes up to 24 weeks before the drug becomes fully effective. Some might also say that it is risky for women to trust their contraception to unwitnessed long-term injections, but men also trust if a woman says she is regularly taking birth control, so trust is operative either way. A reversible male contraceptive may be ideal for men who want to take control of their own fertility choices, regardless of the type of relationship they are in.

**Source:** J Clin Endocrin Metab. 2016, Oct 27. doi: 10.1210/jc.2016-2141).

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#### **Links**

[1] <http://www.cdc.gov/reproductivehealth/contraception/>