

# Did gender bias derail a potential birth control option for men?

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Who's in charge of preventing pregnancy?

For years, available contraception methods have generally made this a woman's responsibility.

But researchers report they may be getting closer to changing the calculation, according to findings published last week in the *Journal of Clinical Endocrinology and Metabolism*. They offered evidence that a new hormonal injection can stop men from producing sperm.

The problem: Three years in, the researchers agreed to terminate the study early, citing potential [side effects](#). That revelation is drawing some criticism.

The approach, which involves an injection of testosterone and progestin every eight weeks, was tested on 320 men in seven countries. Mostly, it worked. But study participants also reported acne, pain, increased [sex drive](#), mood disorders and depression. Those last four symptoms prompted a safety review panel in 2011 to stop the trial from recruiting new test subjects and continuing injections for those already being followed. The research team was allowed, however, to finish data collection and to analyze the findings.

The decision to cease the study has led to a backlash. Some ethicists and advocates say it represents a double standard, citing evidence that female contraception also may be related to depression and other side effects.

They argue men are being protected from the same unpleasant consequences that women are forced to accept.

But how similar are the problems with men's and women's contraception? Here's a break down of the issues and what they mean for the future of male birth control.

Q: First, what actually happened?

A: This study, which began in 2008, is part of a larger effort to develop a form of hormonal birth control for men. Unlike women, who can choose between a host of options - pills, patches, IUDs and implants, to name a few - men seeking temporary birth control can turn only to condoms.

In this case, more than 75 percent of men who completed the trial said they would use it if it were made publicly available.

But there were also 20 participants who dropped out because of the side effects. One committed suicide, though the researchers, citing input from that subject's family, concluded that was likely because of other, unrelated factors.

Because of the safety concerns, research on this particular drug regimen won't continue, said Doug Colvard, who co-authored the study and is deputy director for programs at the nonprofit research organization CONRAD at Eastern Virginia Medical School. The move to discontinue wasn't without criticism, he noted.

"It was disappointing to everyone in the field when the study had to be stopped," he said. "There were people who felt it was justified, and there were people who felt the study shouldn't have been stopped."

Q: So did this actually cause depression in men?

A: Good question. Unfortunately, we don't really know.

That's in part because the trial was stopped early and involved a relatively small sample of men. When testing birth control specifically, it's considered unethical to give a placebo to a control group, because it could result in unwanted pregnancy - meaning there's no real frame against which to compare the results and whether the side effects were indeed caused by this drug, said Jennifer Gunter, a San Francisco-based obstetrician-gynecologist. Gunter was not associated with the study.

Given the lack of information, then, it's tough to draw conclusions either way about how the drug could affect men's mental health.

That said, it wouldn't be surprising if the drug had something to do with these side effects, Gunter said. Testosterone is known to cause acne and to increase sex drive, and it's an anabolic steroid, which also is known to often cause mood problems.

But on the other hand, it's entirely possible some of the negative consequences were caused by factors other than the injection itself, noted Chelsea Polis, a senior research scientist at the Guttmacher Institute, which focuses on reproductive health and health policy. She was not involved in the study. "Adverse events reported in clinical trials include those that are unrelated to the medication, those that are related to the medication, and everything in between," she said.

Q: But hold on. Don't women on hormonal birth control face mental health-related side effects?

A: That's the argument many people are making. But it turns out, the comparison isn't so simple.

Anecdotally, many women say taking hormonal birth control, such as the

pill, led to depression or mood swings. But there's no research definitively making that link. A study published in September was reported to link depression and hormonal birth control in teenage girls.

But scientists caution the relationship is hardly causal. That study, many have noted, measured a fairly small increase in depression and could have been confounded by other factors.

Comparing the discontinued men's study to what we know - or don't know - about how hormonal contraception affect women isn't really feasible, experts said. And, since there historically hasn't been a lot of research on hormonal birth control in men, Gunter said, a cautious approach is in fact responsible and makes a good deal of sense.

Q: Is this going to put the brakes on contraception for men?

A: Probably not.

There's still research underway to develop a hormonal option, Colvard noted. And many researchers said this trial provides potentially helpful insight.

For instance, future research could look at smaller doses, said Cora Breuner, a pediatrician in Seattle who chairs the committee on adolescents for the American Academy of Pediatrics. When female birth control was first developed, researchers began with 50 microgram doses, before working down to 20. Breuner was not involved in the study.

When developing [birth control](#), researchers often start with a high dose, Gunter said. Then, they treat it "like pick-up sticks" - continually reducing the dose until they reach the minimum level necessary to be effective. "How many things can you pull out before the thing falls down?"

Also encouraging: the fact that so many men said they would take the drug if it were available. Historically, the burden of controlling pregnancy has fallen on women, Breuner said. But now, the findings here show that may be shifting - and could in fact spur more interest on the part of drug developers.

"The interest is very much there," she said. "In five years, we'll see a world where the female gender doesn't have to take primary responsibility. ... If the family wants to plan a pregnancy, they can plan it together."

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