# Title: **Male birth control shot found effective, but side effects cut study short**

# (CNN) Nov. 1 by By Susan Scutti

# Both men and women are responsible for pregnancy, yet the burden of preventing it often falls on one gender. Women can choose from a variety of options to control fertility while for generations, men have been limited to withdrawal, condoms and sterilization. But someday soon, a new method may allow men to shoulder a greater share of responsibility.

# A new hormonal birth control shot for men effectively prevented pregnancy in female partners, a [new study](http://press.endocrine.org/doi/pdf/10.1210/jc.2016-2141) found.

# The study, co-sponsored by the United Nations and published Thursday in the Journal of Clinical Endocrinology and Metabolism, tested the safety and effectiveness of a contraceptive shot in 320 healthy men in monogamous relationships with female partners. Conducted at health centers around the world, enrollment began on a rolling basis in September 2008. The men, who ranged in age from 18 to 45, underwent testing to ensure that they had a normal sperm count at the start.

# The injection, given every eight weeks, consisted of 1,000 milligrams of a synthetic form of testosterone and 200 milligrams of norethisterone enanthate, essentially a derivative of the female hormones progesterone and estrogen referred to as "progestin" in the synthetic form.

# According to Dr. Seth Cohen, a urologist at NYU Langone Medical Center, when a man is given a shot of testosterone, "basically, the brain assumes the body is getting enough," so the body shuts down its own production of testosterone -- specifically "the testicle's production of testosterone as well as the testicle's production of sperm."

# The progestin "further drives the brain malfunction, so it stops the testicle's production of both testosterone and sperm," explained Cohen, who was not involved in the new study.

# The researchers used a combination of hormones in order to reduce the testosterone dose to a level that they believed, based on previous studies, would effectively lower fertility yet still be safe.

### Study terminated early

# During the ramp-up pre-efficacy stage of the study, the couples were instructed to use non-hormonal birth control methods, while the men participants received shots and provided semen samples until their sperm counts dropped to less than 1 million per milliliter in two consecutive tests. At that point, couples relied on the injections as contraception.

# Throughout the study, the men provided semen samples to ensure that their sperm counts stayed low. Once the participants stopped receiving the injections, they were monitored to see whether and how quickly their sperm counts recovered to levels described as "[fertile" by the World Health Organization](https://www.ncbi.nlm.nih.gov/pubmed/19934213).

# The researchers discovered that the shot effectively held the sperm count at 1 million per milliliter or less within 24 weeks for 274 of the participants. The contraceptive method was effective in nearly 96% of continuing users.

# Four pregnancies (resulting in three live births) occurred among the men's partners, all during the phase where other contraception was required. All the babies were normal, noted Doug Colvard, co-author of the study and deputy director for programs at the nonprofit research organization [CONRAD, Eastern Virginia Medical School](http://www.conrad.org/about-network-staff-14.html), a co-sponsor of the study.

### Possibly too effective?

# Serious negative effects resulting from the shots included one case of depression and one experience of an abnormally fast and irregular heartbeat after the injections stopped. The researchers considered one intentional overdose of acetaminophen possibly related.

# "It is possible that the fluctuations in the circulating progestin following bimonthly injections could have resulted in the reported or observed mood swings, such as occurs in women, whether on a hormonal contraceptive or not," Colvard speculated.

# Overall, 20 men dropped out early due to side effects. A total of 1,491 adverse events were reported by participants, including injection site pain, muscle pain, increased libido and acne. The researchers say that nearly 39% of these symptoms -- including one death by suicide -- were unrelated to the shots.

# After the shots stopped, most of the men returned to fertility during a recovery period.

# "The minimum recovery time was about 12 weeks after the last injection, and the average time was about 26 weeks," said Colvard.

# Still, there were problems. After 52 weeks in recovery, eight participants had not returned to fertility. The researchers continued to follow these men individually, and five eventually regained normal sperm counts over a longer period of time. One volunteer did not fully recover within four years, though he did "partially recover, so whether he is actually fertile is not known," Colvard said.

# "It shows that it's a risk, a low-probability risk of it, and it's not to be sneezed at as a risk of it, surely," said Elisabeth Lloyd, a faculty scholar at the Kinsey Institute, professor of biology and an adjunct professor of philosophy at Indiana University Bloomington. She is unaffiliated with the new study.

# Lloyd said, adding that this risk needs to be compared with those involved in hormonal birth control for women, such as potentially fatal strokes and blood clots.

# "These risks of fertility damage are not fatal risks like the women endure with their birth control," said [Lloyd](http://mypage.iu.edu/~ealloyd/). "You have to compare what women are doing in terms of taking hormones with what men are doing in terms of taking hormones. Are they taking their life in their hands when they take the hormones? Women are. And that needs to be put right up in front when considering the risk."

# Colvard and his co-authors say more research is needed as they work to perfect their cocktail of hormonal contraceptives in an attempt to reduce the risk of side effects, including depression, increased sex drive and acne.

# Despite the side effects of the male birth control shot, more than 75% of participants reported being willing to use this method of contraception at the conclusion of the study.

# Cohen believes at least part of the reason for this is that they were getting testosterone.

### Looking to the future

# "Testosterone makes men feel pretty good," Cohen said. "Testosterone is not a stimulant per se, but it is a steroid, and like a lot of steroids, it can give you a boost of energy. It can give you a boost of muscle mass. It can help with weight loss. It can help with mentation," or mental activity.

# Lloyd believes that if 75% of the men said they'd be interested in getting the shot if it were available, there's real interest in the product. "That's unbelievable. That's fabulous. I'm very very impressed with that number," she said.

# Cohen, who says he he sees patients who face infertility or other hormonal problems, worries about the safety of this method. "Let's just say, when I read it, I was highly alarmed," he said, explaining that putting men on testosterone who have normal testosterone levels is not safe and amounts to a violation of the "ethical clinical practice guidelines."

# However, Lloyd thinks this product is a long time coming. "It's been a long time since people have been talking about male birth control. This goes back to the 1950s at least." When scientists first began talking about hormonal birth control for women, they also discussed the same for men, explained Lloyd, but hormonal contraceptives for men were not acted on or investigated.

# Cohen questions the general safety of hormonal birth control -- for anyone.

# "We're talking about young people, and the scary thing is messing around with young people's hormones, and that can be detrimental for the rest of their life, right?" Cohen said. "You take an 18-year-old girl or a 20-year-old boy and mess around with their hormones, you've really altered possibly how they go through their life.

# "If anything, this may wake us up to finding out better hormonal contraceptives for women, right? Because certainly, I know that a lot of young women don't get the type of counseling that maybe they deserve when it comes to contraception," Cohen said. "Just a (prescription) and a visit to Duane Reade is all they get, and that may not be enough."

# **Colorado’s Effort Against Teenage Pregnancies Is a Startling Success**

July 5, 2015 by Sabrina Tavernese. New York Times.

WALSENBURG, Colo. — Over the past six years, Colorado has conducted one of the largest experiments with long-acting [birth control](http://health.nytimes.com/health/guides/specialtopic/birth-control-and-family-planning/overview.html?inline=nyt-classifier). If teenagers and poor women were offered free intrauterine devices and implants that prevent [pregnancy](http://topics.nytimes.com/top/news/health/diseasesconditionsandhealthtopics/pregnancy/index.html?inline=nyt-classifier) for years, state officials asked, would those women choose them?

They did in a big way, and the results were startling. The birthrate among teenagers across the state plunged by 40 percent from 2009 to 2013, while their rate of abortions fell by 42 percent, according to the[Colorado Department of Public Health and Environment](https://www.colorado.gov/cdphe). There was a similar decline in births for another group particularly vulnerable to unplanned pregnancies: unmarried women under 25 who have not finished high school.

“Our demographer came into my office with a chart and said, ‘Greta, look at this, we’ve never seen this before,’ ” said Greta Klingler, the family planning supervisor for the public health department. “The numbers were plummeting.”

The changes were particularly pronounced in the poorest areas of the state, places like Walsenburg, a small city in southern Colorado where jobs are scarce and many young women have unplanned pregnancies. Taking advantage of the free program, Hope Martinez, a 20-year-old nursing home receptionist here, recently had a small rod implanted under the skin of her upper arm to prevent pregnancy for three years. She has big plans — to marry, to move farther west and to become a dental hygienist.

“I don’t want any babies for a while,” she said.

More young women are making that choice. In 2009, half of all first births to women in the poorest areas of the state happened before they turned 21. By 2014, half of first births did not occur until the women had turned 24, a difference that advocates say gives young women time to finish their educations and to gain a foothold in an increasingly competitive job market.

“If we want to reduce poverty, one of the simplest, fastest and cheapest things we could do would be to make sure that as few people as possible become parents before they actually want to,” said Isabel Sawhill, an economist at the [Brookings Institution](http://www.brookings.edu/). She argues in her 2014 book, “[Generation Unbound: Drifting Into Sex and Parenthood Without Marriage,](http://www.brookings.edu/research/reports2/2014/09/generation-unbound)” that single parenthood is a principal driver of inequality and long-acting birth control is a powerful tool to prevent it.

Teenage births have been [declining nationally](http://www.hhs.gov/ash/oah/adolescent-health-topics/reproductive-health/teen-pregnancy/trends.html), but experts say the timing and magnitude of the reductions in Colorado are a strong indication that the state’s program was a major driver. About one-fifth of women ages 18 to 44 in Colorado now use a long-acting method, a substantial increase driven largely by teenagers and poor women.

The surge in Colorado has far outpaced the growing use of such methods nationwide. [About 7 percent of American women](http://www.cdc.gov/nchs/data/databriefs/db188.pdf) ages 15 to 44 used long-acting birth control from 2011 to 2013, the most recent period studied, up from 1.5 percent in 2002. The figures include all women, even those who were pregnant or sterilized. The share of long-acting contraception users among just women using birth control is likely to be higher.

But the experiment in Colorado is entering an uncertain new phase that will test a central promise of the Affordable Care Act: free contraception.

The private grant that funds the state program has started to run out, and while many young women are expected to be covered under the [health care law](http://topics.nytimes.com/top/news/health/diseasesconditionsandhealthtopics/health_insurance_and_managed_care/health_care_reform/index.html?inline=nyt-classifier), [some plans have required payment](http://www.nwlc.org/sites/default/files/state_of_womens_birth_control_coverage_key_findings_4.29.152.pdf) or [offered only certain methods](http://www.nwlc.org/sites/default/files/pdfs/stateofbirthcontrol2015final.pdf), problems the[Obama administration is trying to correct](http://www.nytimes.com/2015/05/12/us/health-insurers-ordered-to-heed-law-on-free-contraception-coverage.html?_r=0). What is more, only new plans must provide free contraception, so women on plans that predate the law may not qualify. (In 2014, about a quarter of people covered through their employers were on grandfathered plans, [according to the Kaiser Family Foundation](http://kff.org/report-section/ehbs-2014-summary-of-findings/).)

Advocates also worry that teenagers — who can get the devices at clinics confidentially — may be less likely to get the devices through their parents’ insurance. Long-acting devices can cost between $800 and $900.

“There’s no lifeboat with the Affordable Care Act,” said Liz Romer, a[nurse practitioner](http://topics.nytimes.com/top/news/health/diseasesconditionsandhealthtopics/nursing_and_nurses/index.html?inline=nyt-classifier) who runs the Adolescent Family Planning Clinic at[Children’s Hospital Colorado](http://www.childrenscolorado.org/), which went from giving out 30 long-acting devices a year in 2009 to more than 2,000 in 2013.

The state failed to get additional funding through the General Assembly this spring, a shortfall Ms. Klingler said would slow, but not stop, its progress.

Women’s health advocates contend that long-acting birth control is giving American women more say over when — and with whom — they have children. [About half of the 6.6 million pregnancies a year in the United States are unintended](http://www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.html#6). Teenage births may be down, but unplanned births have simply moved up the age scale, Ms. Sawhill said, and having a baby before finishing college can be just as risky to a woman’s future as having one while in high school.

Colorado’s program, funded by a private grant from the Susan Thompson Buffett Foundation, named for the billionaire investor[Warren Buffett](http://topics.nytimes.com/top/reference/timestopics/people/b/warren_e_buffett/index.html?inline=nyt-per)’s late wife, was the real-world version of [a research study in St. Louis](http://www.nytimes.com/2014/10/02/science/teenage-pregnancy-and-abortion-rates-plummet-with-long-acting-female-contraception-study-says.html) (also paid for by the foundation, which does not publicly acknowledge its role). The study came to the same conclusion: Women overwhelmingly chose the long-acting methods, and pregnancy and [abortion](http://health.nytimes.com/health/guides/surgery/abortion/overview.html?inline=nyt-classifier) rates plunged.

“The difference in effectiveness is profound,” said Dr. Jeffrey Peipert, a professor of obstetrics and gynecology at Washington University in St. Louis, who ran the study. The failure rate for the pill was about 5 percent, compared with less than 1 percent for implants and IUDs.

The methods are effective because, unlike the pill, a diaphragm or[condoms](http://topics.nytimes.com/top/news/health/diseasesconditionsandhealthtopics/condoms/index.html?inline=nyt-classifier), they do not require a woman to take action to work. And while an early incarnation, [the Dalkon Shield](http://www.nytimes.com/1987/12/06/magazine/the-sad-legacy-of-the-dalkon-shield.html) introduced in the 1970s, had disastrous results, the modern devices are safe and have been increasingly promoted by doctors. Last fall, the American Academy of Pediatrics [published guidelines that for the first time singled them](https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/AAP-Updates-Recommendations-on-Teen-Pregnancy-Prevention.aspx) out as a “first-line” birth control option for adolescents, citing their “efficacy, safety and ease of use.”

“There’s been a big shift in the mind-set,” said Dr. Laura MacIsaac, director of family planning for Mount Sinai Beth Israel in New York. “The demand is coming from everywhere now.”

In Walsenburg, studded with boarded-up buildings and weedy parking lots, advocates have used the Buffett grant to help women get more control. Poverty erodes health here: Last year, rural Huerfano County, which includes Walsenburg, [was ranked second to last for life expectancy](http://www.countyhealthrankings.org/app/colorado/2014/rankings/outcomes/1) in the state.

“If you get pregnant here, you are stuck,” said Debbie Channel, the manager of the Spanish Peaks Regional Health Center’s [Outreach and Women’s Clinic](https://www.sprhc.org/outreach-womens-clinic/), where Ms. Martinez, the nursing home receptionist, got her implant. “We’re trying to keep them safe and baby free.”

Proponents say the program is working. The state health department[estimated that every dollar spent](https://www.colorado.gov/pacific/sites/default/files/HPF_FP_UP-Cost-Avoidance-and-Medicaid.pdf) on the long-acting birth control initiative saved $5.85 for the state’s [Medicaid](http://topics.nytimes.com/top/news/health/diseasesconditionsandhealthtopics/medicaid/index.html?inline=nyt-classifier) program, which covers more than three-quarters of teenage pregnancies and births. Enrollment in the federal nutrition program for women with young children declined by nearly a quarter between 2010 and 2013.

Ms. Martinez had a preview of life as a mother while babysitting for two young stepbrothers. She found it exhausting. She watched girls in her high school get trapped when they became mothers too soon, and she knew she did not want that for herself.

“They say they want to leave Walsenburg, but they never do,” she said. “It’s a circle. It keeps happening and happening.”

Ms. Martinez plans to leave town this summer after she marries her fiancé, now in California in military training. She is excited about the next chapter.

“I’m not scared at all,” she said. “I’m just really ready.”

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