

# PUBLICATION OF VASALGEL REVERSAL STUDY

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## Reversal of Vasalgel male contraceptive in rabbits

For immediate release: *Vasalgel's prevention of sperm transport in the vas deferens for 14 months was reversed through an injection of sodium bicarbonate. Sperm concentration and motility returned to baseline.*

Results of a study of a promising new male contraceptive called Vasalgel™ were [published today](#) in *Basic and Clinical Andrology*. The polymer gel is injected into the vas deferens and blocks the passage of sperm. The study followed the progress of seven rabbits successfully contracepted for an average of 14 months before the gel was flushed out. Sperm flow returned in all animals after reversal, confirming unobstructed sperm transit (patency of the vas deferens) and warranting continued development of this product.

## Few current male contraceptive options

When considering reproductive control, couples often rely on female contraceptive methods, including daily pills and long-acting products such as IUDs and implants. However, many women cannot tolerate the side effects of hormonally-based contraceptives and grow frustrated with the downsides of other methods.

Men who wish to control their own reproduction or lift the burden of contraception from their partners have even fewer options. No new male contraceptives have emerged in more

than a century, and men must rely on the old standbys: condoms, which are important for reducing the incidence of sexually transmitted infections in new relationships but result in high pregnancy rates in typical (imperfect) use; withdrawal, which has an even higher pregnancy rate in typical use; and vasectomy, which is very effective but should be considered permanent due to the unpredictability of successful reversal. The need for a long-acting, reversible male contraceptive – without the side effects of hormones – has been demonstrated in international surveys and could be met by Vasalgel.

### **How Vasalgel works**

Vasalgel functions like a reversible vasectomy, blocking or filtering out sperm. The device is implanted into the vasa deferentia (singular: vas deferens) – the small tubes that transport sperm from the testes. It is composed of high molecular weight polymer powder dissolved in dimethyl sulfoxide (DMSO), a biocompatible solvent. The resulting Vasalgel implant remains in a soft gel-like state that allows water-soluble molecules to pass but not larger structures such as spermatozoa. This quality is thought to be a benefit for preventing back-pressure on sperm storage areas. The contraceptive effect lasts for years, and, importantly, is developed to be reversible by a second injection to dissolve the Vasalgel.

### **Demonstration of efficacy and reversibility in rabbits**

In a previous [publication in 2016](#), the research team reported Vasalgel provided effective contraception in rabbits. Vasalgel produced a rapid onset of azoospermia, with no live sperm in semen samples collected as early as 29–36 days post-implantation, and the effect was durable over a 12-month period. The device was safe and was well-tolerated by the rabbits with minimal effects on the structure of the vasa deferentia.

The follow-up study published today reported the results of reversing the contraceptive effect of Vasalgel in the same rabbits. Seven rabbits, successfully contracepted for 14 months following Vasalgel implant, underwent a reversal procedure. A sodium bicarbonate (baking soda) solution was injected into the vasa deferentia of each rabbit to dissolve the implants and clear the blockage. Baking soda is known for its ability to safely neutralize acids. In this case, the bicarbonate solution neutralizes and breaks down the hydrogel structure of the polymer gel. Sperm flow returned quickly, as evidenced by spermatozoa present in the semen of all animals.

Further evaluation of the sperm characteristics after reversal indicated sperm concentrations and sperm motility were similar to baseline levels, an important first step to a return of fertility. The sperm forward progression measurements were significantly lower than the baseline measurements but increased consistently during six months of follow-up semen collection.

Microscopic evaluation of the vasa deferentia indicated that most had an intact epithelial lining (inner lining tissue) and were clear of the gel. A smaller proportion of tissues contained residual gel, and an occasional secondary intraluminal inflammatory response (minor inflammation inside the vas deferens) was observed. Rabbits have unusually large and thus vulnerable acrosomes (caps) on the heads of their sperm, which were not observed following reversal. Residual material may have impacted the sperm forward progression and caused loss of acrosomes during transit through the vas.

“The results of the Vasalgel reversibility study in rabbits indicate the implant could be removed resulting in a quick return of sperm flow,” said lead author Donald Waller, Ph.D. “We were pleased that the number of sperm and their motility after reversal were no different from baseline measures. More flushing during reversal may be needed to remove traces of the gel from the vas deferens, which appeared to impact other sperm characteristics.”

The results of the study provide momentum for continued development of Vasalgel as a male contraceptive.

### **Next steps**

Vasalgel is being developed as a non-hormonal, long-acting, reversible male contraceptive by Revolution Contraceptives, LLC, a social venture subsidiary of Parsemus Foundation, a nonprofit organization based in the San Francisco Bay Area.

Vasalgel has demonstrated efficacy in monkeys and rabbits in previously published studies. This study is the first to demonstrate reversibility. Reversal in larger animals has not been confirmed and is an active research focus.

“This study gave us the confidence to continue development of Vasalgel,” said Elaine Lissner, founder and trustee of Parsemus Foundation. “We flushed out most of the gel and restored full sperm flow. Now the thousands of followers of Vasalgel’s progress are counting on us to refine and repeat this reversal success in larger animals.”

With contraceptive efficacy well-established in multiple species, preparations are being made for the first contraceptive efficacy clinical trials in humans. Parsemus Foundation aims for Vasalgel to be available worldwide, with a tiered international pricing structure to ensure affordability to all men.

To fund the development of Vasalgel, Parsemus Foundation is seeking socially-minded investors and foundation partners who are committed to affordable access. Social venture funding will be critical to meeting the goal of starting clinical trials in 2018. For more information on funding and partnership opportunities, please contact [info@revolutioncontraceptives.com](mailto:info@revolutioncontraceptives.com).

About Parsemus Foundation: Parsemus Foundation works to advance innovative and neglected medical research. Many of the studies the foundation supports involve low-cost approaches that are unlikely to be pursued by pharmaceutical companies due to limited profit potential. Successful studies to date have included breast cancer treatment advances, low-cost readily available nonsurgical dog and cat sterilization, and non-invasive treatment of benign prostatic hyperplasia using a currently marketed device. Parsemus Foundation's current main focus is bringing Vasalgel to market.

**Images, key facts, and statistics:** see <http://revolutioncl.com/news/media-resources/>