

Contraline's First In-Human Trial Shows Safety with 12-Month Efficacy Signals of the ADAM™ Male Contraceptive Device

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[Contraline](#), a clinical-stage biotechnology company, has announced promising initial safety and efficacy results from its First-in-Human clinical trial. The trial, which is evaluating the safety and preliminary efficacy of Contraline's ADAM™, a non-permanent male contraceptive, has had its first patients demonstrate 12 months of efficacy in the study.

ADAM™ is a water-soluble, biocompatible, and non-permanent hydrogel that is implanted into the vas deferens where it blocks sperm transport, resulting in azoospermia (no sperm in the ejaculate). ADAM™ has the potential to be the first male contraceptive option beyond condoms (single-use) and vasectomy (permanent).

Earlier this year, Contraline completed enrollment of an open-label, multicenter trial, with 25 participants across three sites in Australia. ADAM™ continues to demonstrate a favorable safety profile, with no reports of treatment-related serious adverse events. All adverse events (AEs) have been anticipated and a majority of the AEs have been mild. Additionally, no AEs have been related to ADAM™ hydrogel.

Contraline previously reported that within 30 days of ADAM™ implantation, a 99.8-100.0% reduction in the number of motile sperm was observed, demonstrating that ADAM™ can lower sperm concentration and motility to levels comparable to vasectomy in a short amount of time.¹



Contraline is now reporting that patients in the study are demonstrating azoospermia 12 months after implantation, providing an initial signal for ADAM™ as a long-term contraceptive option.

There is a significant demand from patients seeking long-lasting, reversible male contraception, a gap that ADAM™ may fill. Approximately 17-20 million men in the United States are actively seeking to use new forms of male contraception,² and the percentage of younger men getting vasectomies has significantly increased since the overturn of Roe v. Wade, supporting the demand for safe, long-lasting alternatives.³ Market research studies have shown that men have the strongest preference for a one year contraceptive duration (n=1,500).⁴ Contraline's market research confirmed these results, with 35% of men choosing 1-2 years as their primary preference for an implantable male contraceptive, followed by 6-months and 3-5 years.

Prof. Nathan Lawrentschuk, Principal Investigator of the clinical trial, shared his perspective on the achievement, stating, "The results of Contraline's first in human clinical trial are promising. The ADAM™ hydrogel has a tremendous safety profile and with patients showing efficacy signals over a 12-month period, there is potential to address the longstanding need for long-lasting, safe, and reversible male contraception."

Dr. Alex Pastuszak, Chief Medical Officer at Contraline, expressed his enthusiasm about the results, stating, "These efficacy results support the conclusion that 12 months of efficacy is possible using the ADAM™ hydrogel, marking a significant milestone in the development of novel, flexible male contraceptive options."

These promising First-in-Human results pave the way for further advancements in male reproductive health. Contraline is planning on conducting an Early Feasibility Study on the ADAM™ hydrogel, which is slated to initiate in Q1 2025.

Disclaimer

ADAM™ is an investigational device and is not yet approved by the U.S. Food and Drug Administration (FDA) or any other regulatory authority worldwide. As such, ADAM™ is not available for commercial use at this time. The device's safety and effectiveness have not been established, and it is currently available only for investigational use in approved clinical trials.

About Contraline

Contraline, Inc. is a venture-backed, clinical-stage, biotechnology company focused on innovation in reproductive health. The company is developing ADAM™, the world's first injectable hydrogel designed to provide long-lasting, non-hormonal, and reversible contraception for men. To learn more, visit www.contraline.com

References

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https://www.malecontraceptive.org/uploads/1/3/1/9/131958006/mci_consumerresearchstudy.pdf

³ <https://www.latimes.com/science/story/2024-05-14/younger-patients-sought-vasectomies-after-roe-vs-wade-overturned>

⁴ <https://pubmed.ncbi.nlm.nih.gov/15608042/>

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