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SHORT REVIEW

# The modern male contraception is no longer a utopia

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## Abstract

Despite significant advances in reproductive health, male contraceptive options remain limited to condoms, withdrawal, and vasectomy. While these methods are effective, each of them has important limitations, highlighting the need for additional safe, effective, and reversible male contraceptive approaches. This review provides an overview of the current landscape of male contraception and summarizes recent developments in both hormonal and non-hormonal strategies. Promising hormonal candidates include transdermal testosterone/segesterone (Nestorone®) gel, dimethandrolone undecanoate (DMAU), and 11β-methyl-19-nortestosterone derivatives, several of which have progressed to clinical trials. Emerging non-hormonal approaches target specific mechanisms involved in sperm production, maturation and function, including retinoic acid signaling, epididymal peptidase inhibitor (EPPIN), and soluble adenylyl cyclase (sAC). Additional innovative strategies include reversible vas deferens occlusion techniques, such as RISUG-derived technologies and hydrogel implants, as well as thermal contraception. Although most of these methods remain in phase of clinical or preclinical evaluation, recent progress suggests that effective and reversible male contraceptive options may become available within the upcoming decade. Continued research, investment, and stakeholder engagement will be essential to translate these advances into clinical practice.

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## Introduction

“The unintended pregnancy rate is about 50% of all pregnancies worldwide. At present the responsibility of preventing unintended pregnancies falls almost entirely on women.” [1]

According to the 2019 United Nations report on contraception, the global prevalence of male contraceptive use was approximately 28%, with condoms accounting for 21%, withdrawal for 5%, and vasectomy for 2% [2]. Despite their widespread use, these methods are associated with well-recognized limitations and disadvantages that have been extensively documented in the literature.

In 2023, an estimated 218 million women experienced an unmet need for contraception, and every day approximately 810 women died from preventable causes related to pregnancy and childbirth [3]. Up until now, there is an expressed demand among both men and women for a highly effective, low-maintenance, and well-tolerated male contraceptive option.

The International Consortium for Male Contraception (ICMC) was established on September 13, 2013, with the primary objective of advancing awareness of male contraception and promoting progress in the field. As an advocacy organization, the ICMC also seeks to foster support among the public and the medical community for the development, introduction, and acceptance of modern male contraceptive methods.

### *Future hormonal male contraception*

Numerous hormonal male contraceptive agents are currently undergoing various stages of clinical development. Investigational single-agent compounds, including dimethandrolone undecanoate (DMAU) and 11β-methyl-19-nortestosterone 17β-dodecylcarbonate (11β-MNTDC), have successfully completed Phase I of clinical trials. In addition, a contraceptive efficacy trial of Nestorone®/testosterone gel is currently underway, awaiting Phase III evaluation. In contrast, the development of non-hormonal male contraceptive approaches remains confined to the preclinical stage [4] (Table 1).

**Table 1.** Research in Male Contraception reproduced from Serfaty D, 2024 [4].

| Male modern contraceptive method | Status of research advancement |
|---|---|
| NES/T gel | Completed Phase II, Awaiting start of Phase III |
| DMAU Oral | Completed Phase I |
| 11βMNTDC Oral | Completed Phase I and II |
| DMAU Injectable | Completed Phase I |
| Pill YCT-529 (Your choice) | Currently in Phase I |
| Epididymal peptidase inhibitor (EPPIN) | Not yet entered human clinical trials |
| Adenylyl cyclase soluble (ADCY10) | Not yet entered human clinical trials |
| Plan A (formely Vasalgel) | In Phase II of clinical human trials |
| ADAM hydrogel | Currently in Phase I |

Table 2 summarizes the principal efficacy outcomes of clinical trials evaluating hormonal male contraceptive methods, predominantly injectable formulations, conducted under the auspices of the World Health Organization (WHO). It is noteworthy that the most recent trial, conducted collaboratively by the WHO and CONRAD, investigated the efficacy of combined testosterone undecanoate and norethisterone enanthate administration and demonstrated encouraging contraceptive efficacy. However, the study was terminated prematurely following the recommendation of an external safety review committee due to the incidence of reported adverse effects, including mood changes, depression, injection site pain, and increased libido [5].



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**Table 2.** Male hormonal contraceptive efficacy trials reproduced from Long JE, et al. 2021 [5].

| Contraceptive regimen | Number registered (N) | Number accepted/ completing the trial | Pregnancies | Failure rate (per 100 couple-years) | Study / Sponsor |
|---|---|---|---|---|---|
| Weekly testosterone enanthate injection | 271 | 157 / 119 | 1 | 0.8 (0.0-4.5) | WHO, 1990 |
| Weekly testosterone enanthate injection | 357 | 268 / 209 | 4 | 1.4 (0.4-3.7) | WHO, 1996 |
| Monthly testosterone undecanoate injection | 308 | 296 / 280 | 1 | 2.3 (0.5-4.2) | Gu et al., 2003 |
| Monthly testosterone undecanoate injection | 1045 | 855 / 733 | 9 | 1.1 (0.4-1.8) | Gu et al., 2009 |
| Testosterone implant every 4-6 months + depot medroxyprogesterone acetate injection every 3 months | 55 | 53 / 28 | 0 | 0 (0-8) | Turner et al., 2003 |
| Testosterone undecanoate injection + norethisterone enanthate injection every 8 weeks | 320 | 266 / 111* | 4 | 2.2 (0.8-5.8) | WHO/CONRAD; Behre et al., 2016 |
| Daily transdermal testosterone + nestorone gel | Ongoing | Ongoing | Ongoing | Ongoing | NICHD |

**Trial prematurely interrupted*

In light of the evidence summarized above, three hormonal male contraceptive strategies may be regarded as the most promising candidates for future clinical use:

- Transdermal gel of testosterone and nestorone (NES/T gel), now ready for Phase III [6]. It has the potential of becoming the first modern, daily, self-administrable hormonal male contraception on the market.
- DMAU and 11ß-MNTDC - contraceptive pills for men based on progestogenic androgens [7] (Figures 1a and 1b).
- Injectable DMAU - long-acting, intramuscular injection, which has completed Phase I.

**Figure 1a.** Metabolic activation of dimethandrolone undecanoate (DMAU).

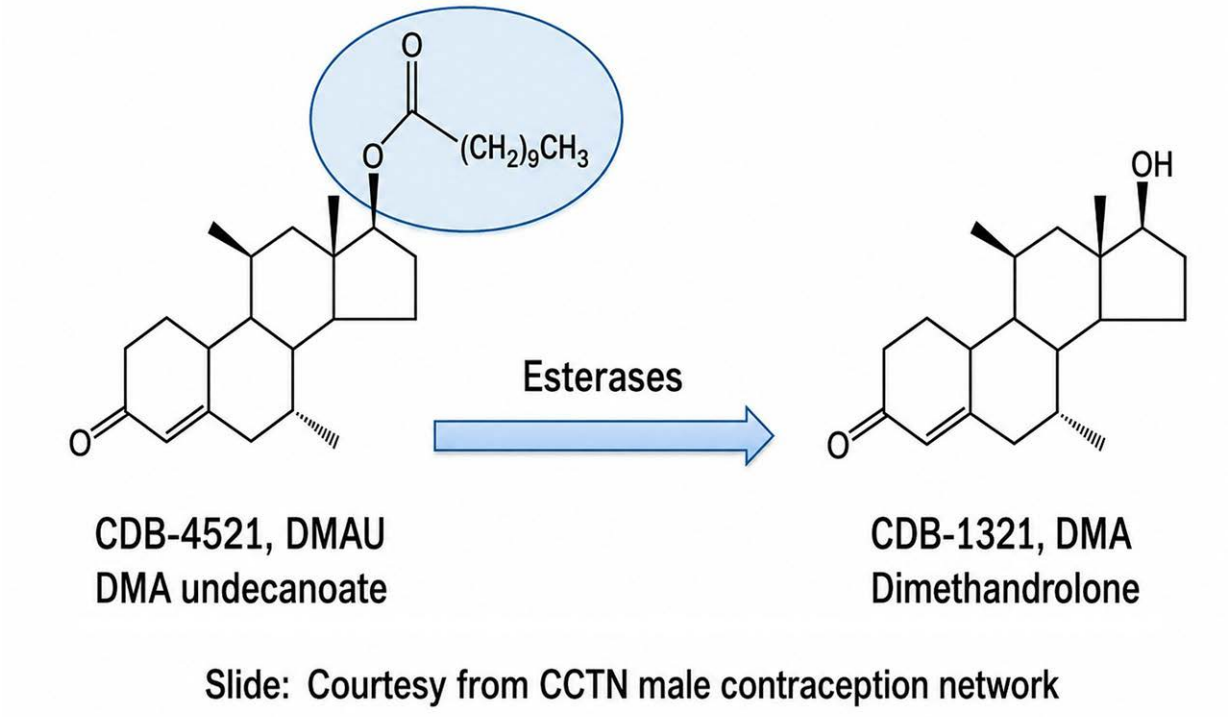




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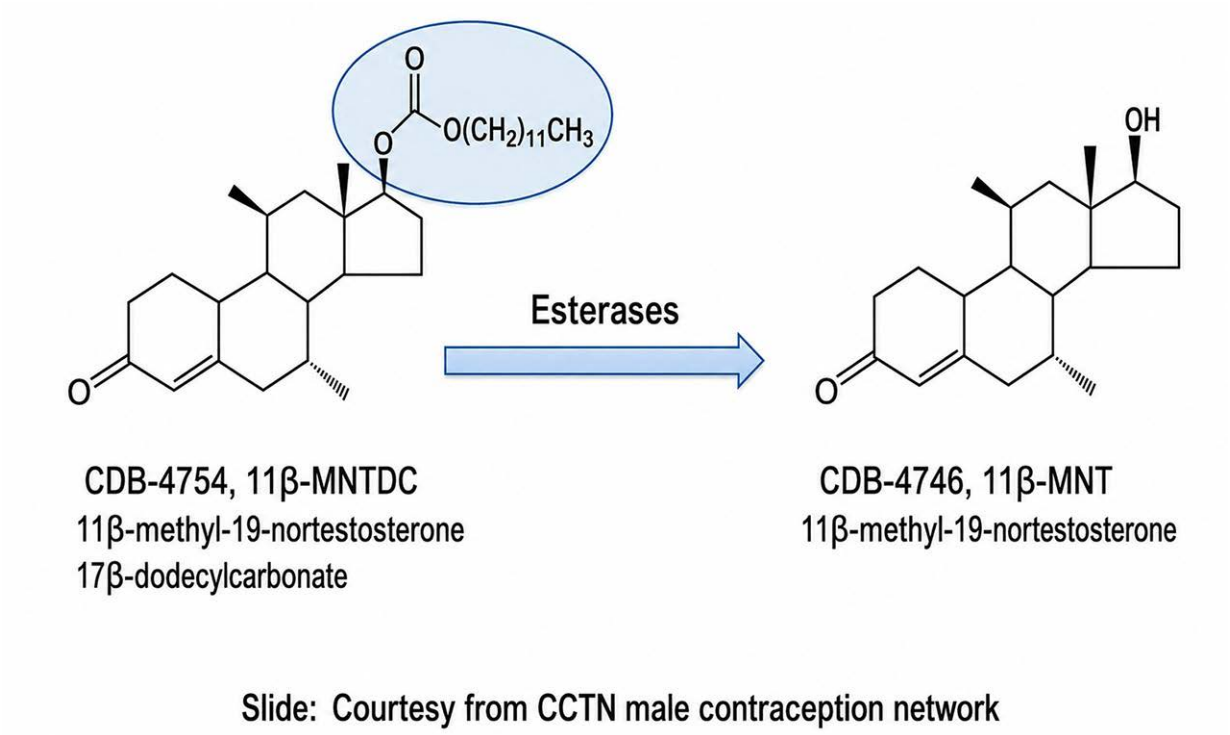
**Figure 1b.** Metabolic activation of 11β-methyl-19-nortestosterone dodecylcarbonate (11β-MNTDC).




### *Future non-hormonal male contraception*

While hormonal male contraception suppresses spermatogenesis by modulating the hypothalamic–pituitary axis through negative feedback [8], non-hormonal male contraception aims to bypass this endocrine pathway. Instead, it acts directly on the testes or the male reproductive tract, thereby avoiding the potential adverse effects associated with hormonal interventions. Current research is focused on inhibitors or antagonists of key mechanisms involved in male reproductive processes [5]. Among these non-hormonal contraceptive strategies, the following approaches merit particular consideration:

1. A pill YCT-529 (“YourChoice”), based on an oral inhibitor of retinoic acid begins a Phase I on men. Insufficiency of retinoic acid can impair sperm production. YCT-529 represents a promising candidate that could become the first orally administered non-hormonal male contraceptive to reach the market.
2. EPPIN (epididymal peptidase inhibitor), a sperm surface protein involved in the regulation of sperm motility and function [5,9]. Targeting EPPIN represents a potential non-hormonal strategy aimed at impairing sperm function without altering systemic hormonal pathways.
3. Soluble Adenylyl Cyclase (sAC), an enzyme involved in sperm maturation, motility, and fertilization capacity. Pharmacological inhibition of sAC has demonstrated contraceptive potential in preclinical studies and may represent a pathway toward the development of an on-demand, non-hormonal male contraceptive [5,10-11].

### *Future male contraception by reversible non-surgical obstruction (RISUG) of vas deferens*

RISUG (Reversible Inhibition of Sperm Under Guidance), a male contraceptive method that has been investigated in India since the 1970s, and Vasalgel, both involve the injection of a polymer styrene maleic anhydride, dissolved in dimethyl sulfoxide (DMSO), into the vas deferens. Vasalgel, a contraceptive product derived from the RISUG concept, is designed to function as a physical barrier that prevents the passage of sperm through the vas deferens. The restoration of vas deferens permeability can be achieved by injecting a sodium bicarbonate solution. Preclinical studies evaluating this reversal approach have been completed in animal models, including rabbits and monkeys [5,12]. In 2023 Vasalgel was licensed for further development as Plan A reversible male contraceptive, and clinical trials on men have been initiated in Quebec (Canada).

A hydrogel-based contraceptive approach, known as the ADAM™ system, has been developed as a biodegradable implant designed to obstruct sperm transport while allowing the passage of other fluids. The



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hydrogel is injected directly into the vas deferens, where it forms a temporary barrier with a reported duration of action ranging from approximately 6 to 24 months. Notably, the hydrogel can be dissolved if desired, providing the potential for restoration of vasal patency and fertility. This approach may represent a biodegradable intra-deferential device (DID), offering a potential reversible, non-hormonal alternative to conventional male contraceptive methods [5].

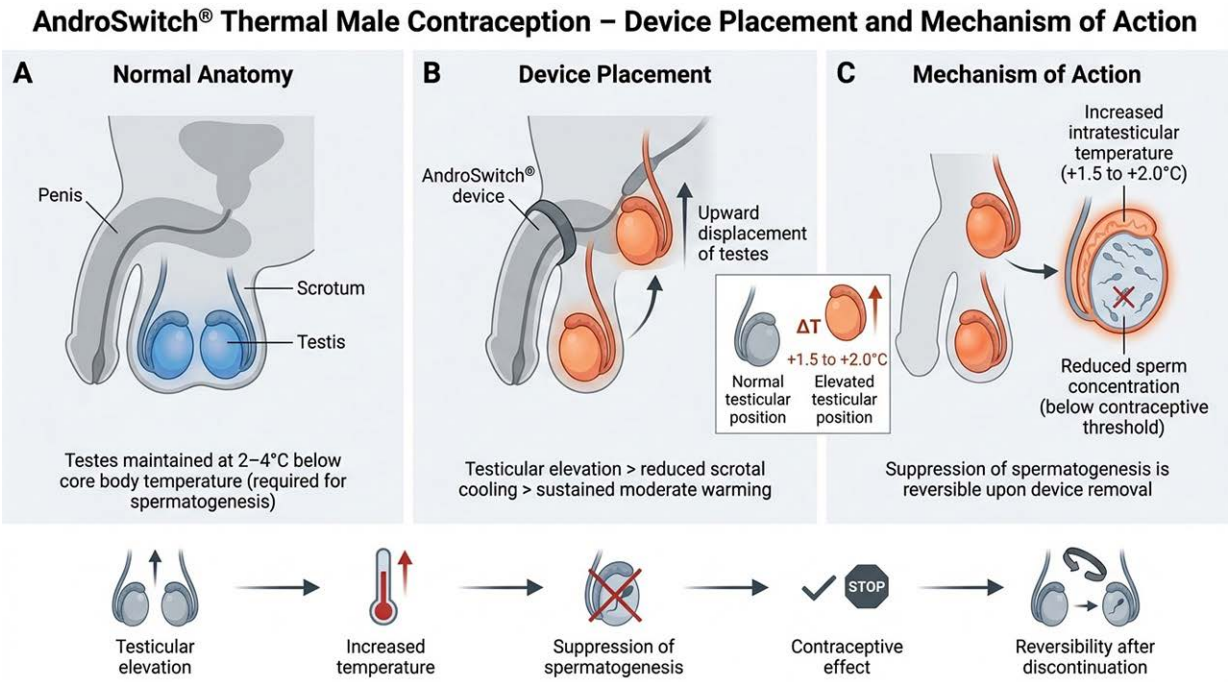
### *Male thermal contraception*

Male thermal contraception is a non-hormonal method based on the physiological sensitivity of testicular exocrine function (spermatogenesis) to moderate increases in testicular temperature. By maintaining the testes within the inguinal pouch, the method induces a sustained elevation in testicular temperature sufficient to impair sperm production while preserving endocrine function. This approach has been extensively investigated over the past four decades by the Andrology Research Group at the University of Toulouse (France), led by Roger Mieusset [13].

Several devices designed to elevate the testes into the inguinal pouch are currently under development. Among these devices there are the “Toulouse Underwear” (also referred to as the “Mieusset Heating Underwear”), developed by the research team at Toulouse University, as well as the “Thermal Underwear”, and the “Andro-switch” ring developed by Maxime Labrit.

Andro-switch is a penoscrotal support device designed to maintain the testes in a higher position within the inguinal pouch, thereby increasing scrotal temperature and inducing suppression of spermatogenesis. The device is intended to be worn for approximately 15 hours per day. Contraceptive efficacy is expected to be achieved after approximately 2-3 months of continuous use, corresponding to the duration required for the reduction of sperm production (Figure 2). The Andro-switch device is currently undergoing the certification process. The thermal male contraception appears to be an efficient and well tolerated method for highly motivated users. Nevertheless, its safety profile, particularly its carcinogenic safety, still needs to be confirmed [13].

**Figure 2.** Andro-switch thermal male contraception: device placement and proposed mechanism of action.




## Conclusion on the male contraception of tomorrow

The need for male contraception is unquestionable and its future is promising; however, with the exception of the combined testosterone/nestorone gel and the oral contraceptive YourChoice pill, it is not certain whether any of the emerging male contraceptive methods will become commercially available before 2030. This timeline could be accelerated through increased financial investment in male contraceptive research, accompanied by greater commitment and engagement from all stakeholders, men and women alike.



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### *Declaration of interest*

The author declares no conflict of interest

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None

## Figure legend

**Figure 1a.** Metabolic activation of dimethandrolone undecanoate (DMAU).

**Figure 1b.** Metabolic activation of 11β-methyl-19-nortestosterone 17β-dodecylcarbonate (11β-MNTDC).

**Figure 2.** AndroSwitch® thermal male contraception: device placement and proposed mechanism of action.

(A) Normal anatomy. Schematic representation of the male external genitalia under physiological conditions. The testes are located within the scrotum, maintaining a temperature approximately 2 to 4°C below core body temperature, which is required for normal spermatogenesis.

(B) Device placement. The AndroSwitch® device is positioned at the penoscrotal junction, elevating the testes toward the superficial inguinal region. This upward displacement reduces scrotal cooling and produces a sustained, moderate increase in testicular temperature. The device is intended to be worn daily for prolonged periods (typically approximately 15 hours per day).

(C) Mechanism of action. Testicular elevation results in a reversible increase in intratesticular temperature, leading to progressive suppression of spermatogenesis. Following several weeks of continuous use, sperm concentration decreases below the contraceptive threshold. Upon discontinuation of thermal exposure, spermatogenic activity is expected to recover gradually, restoring fertility.

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