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Design Of An International Male Contraceptive Efficacy Trial Using A Self-administered Daily Topical Gel Containing Testosterone And Nestorone™

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Support: Supported by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) through the Contraceptive Development Program's Contraceptive Clinical Trials Network and by the Population Council. **Background:** A self-administered male hormonal contraceptive might be very useful to prevent unintended pregnancy. Prior efficacy studies of male hormonal contraceptives have relied on injections or implants of hormones by medical personnel. Transdermal testosterone gels are widely used to treat hypogonadism. Transdermal administration may have utility for male contraception as well; however, no contraceptive efficacy data from the use of a self-administered transdermal male hormonal contraceptive gel are available. Survey data suggests that men are not only interested in male contraception but that a self-administered transdermal gel is desired by many men as an optimal form of contraceptive delivery. A transdermal male contraceptive raises novel considerations regarding compliance with and absorption of the gel in men as well as concern regarding the potential cutaneous transfer of the hormones to the female partner. Previous studies in men have demonstrated that a combined Nestorone-(segesterone acetate) testosterone transdermal gel is well tolerated, and that it safely and effectively suppresses sperm production to contraceptive levels in men who apply it daily. Here we describe the design of an ongoing Phase 2b safety and efficacy trial of this transdermal male contraceptive gel. We discuss the novel aspects and challenges in the design and evaluation of an international transdermal male contraceptive efficacy study that was conducted during a global pandemic. **Methods:** We are conducting an international, single-arm, open-label study of self-administration of a daily combined Nestorone (segesterone acetate)-testosterone gel for male contraception. Couples are eligible for the study if they are in a committed relationship, at risk for unintended pregnancy and the men have normal spermatogenesis and are in good health. The primary outcome is the rate of pregnancy in couples during the 52-week efficacy phase of the study. Secondary endpoints include the proportion of men suppressing sperm production and entering the efficacy phase, side effects, hormone concentrations in both men and their female partners, sexual function, urinary symptoms, and regimen acceptability for the men and their female partners. *ClinicalTrials.gov*: NCT03452111. **Results:** Approximately 460 couples have been enrolled at 17 sites internationally including sites in North and South America, Europe and Africa. The study is now closed to enrollment. **Conclusions:** We present the design of the first study to examine contraceptive efficacy, side effect profile and acceptability of a self-administered, reversible, male hormonal contraceptive product.

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