Herman Behre & Mario Festin

WHO Efficacy and Safety study

First International Congress on Male Contraception
ICMC, May 4, 2016, Paris, France

WHO Efficacy and Safety study (1)

Objective: Evaluation of the rate of suppression of spermatogenesis and the level of contraceptive protection by intramuscular injections of the progestogen norethisterone enantate (NET-EN) combined with the androgen testosterone undecanoate (TU), administered every eight weeks.

Design: Prospective multicenter study.

Setting: Ten study centres in seven countries and four continents.

Participants: Healthy men, aged 18 to 45 years, and their 18 to 38 year-old female partners, both without known fertility problems and in stable, monogamous relationships, along with a coital frequency of twice/week on average.

First International Congress on Male Contraception
ICMC, May 4, 2016, Paris, France

WHO Efficacy and Safety study (2)

Results:

- Of the 320 participants, 95.9 of 100 continuing users (95% CI: 92.8 to 97.9) suppressed to a sperm concentration ≤ 1 million/ml within 24 weeks (Kaplan-Meier method).
- During the efficacy phase of up to 56 weeks, four pregnancies occurred among the partners of the 266 male participants, with the rate of 1.57 per 100 continuing users (95% CI: 0.59 to 4.14).
- The cumulative reversibility of suppression of spermatogenesis after 52 weeks of recovery was 94.8 per 100 continuing users (95% CI: 91.5 to 97.1).
- The most common adverse events were acne, injection site pain, increased libido, and mood disorders.
- Following the recommendation of an external safety review committee the recruitment and hormone injections were terminated early.