## Study on sperm suppression using Norethisterone enanthate and testosterone undecanoate

### Objectives and Background

**Overall goal:**
The study was designed to address the following primary objectives:

1. The rate of **suppression of spermatogenesis** induced by a regimen of NET-EN and TU administered every 8 weeks for up to 4 injection visits; and
2. The level of **contraceptive protection** provided by the continued administration of NET-EN and TU every 8 weeks for an efficacy period of up to 56 weeks.

**Background:**
The study was designed to evaluate whether the combination of a progestin, norethisterone enantate (NET-EN), and an androgen, testosterone undecanoate (TU), represents a safe and effective method of male fertility regulation.

The study had 3 phases. The suppression phase was to initiate a status of decreased sperm count and activity to a level which would be considered as contraceptive. When this was reached it was sustained with subsequent injections in the efficacy phase, which would end after 56 weeks, or if a pregnancy occurs. After these, the participant was then placed in the recovery phase, and was observed until normal sperm counts and activity returns to normal.

487 participants were screened for eligibility, of which 167 were excluded. The remaining 320 were enrolled into the study, into the suppression phase. A total of 274 completed the suppression phase. Of these 8 discontinued before transitioning to the Efficacy phase, and were moved to recovery phase. A total of 266 transitioned to the efficacy phase, among which 111 completed 56 weeks follow up or until a pregnancy occurred. The remaining 155 were discontinued, either because of the stopping of the study by the sponsor (96), death (1, unrelated to the study), or for other reasons (58).

A total of 279 of the above participants were transitioned to the recovery phase (either from the suppression phase or the efficacy phase)

### Geographic location

Jakarta, Indonesia; Halle, Germany; New Delhi, India; Bologna, Italy; Melbourne, Australia; Sydney, Australia; Manchester and Edinburgh, UK

### Main deliverables

A technical clinical study report has been submitted to the EMA. A scientific paper for journal publication is being prepared for submission by first quarter 2015.

### Partners

Conrad, Virginia USA.

### Sources of funding

HRP

Contact reproductivehealth@who.int  [http://www.who.int/reproductivehealth/en/]