



## UNINTENDED PREGNANCIES IN USERS OF DIFFERENT COMBINED ORAL CONTRACEPTIVES – FINAL RESULTS FROM THE INAS-SCORE STUDY

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**Background:** Oral contraceptives are the most popular method of birth control and widely used. The effectiveness is compared between different combined oral contraceptives in Europe.

**Objectives:** To compare the contraceptive failure rates between the two user cohorts: estradiol valerate / dienogest (EV / DNG) containing COC (combined oral contraceptive) compared to established COCs

**Methods / Patients:** Large, prospective, controlled, non-interventional cohort study. It was conducted from 2009 to 2016 in the US as well as in 6 European countries. Women were enrolled by their prescribing physician.

**Interventions:** non-interventional study

**Main outcomes:** During the follow-up phase, women were contacted every 6 to 12 months for a maximum of 6 years and asked for information about unintended pregnancy (secondary outcome). Self-reported pregnancies were validated by health care professionals. Incidence rates (per 10,000 WY), rate ratios, and Pearl Indices were calculated. Inferential statistics were based on Cox proportional hazards models. As requested by the European Medicinal Agency, final analyses are based on the European data only.

**Results:** The last interim analysis in September 2016 was based on 71,2952 WY of hormonal contraceptive exposure. Overall, 253 unintended pregnancies were reported, of which 29 occurred under Qlaira use (Pearl Index: 0.2; 95% CI: 0.1-0.3) and 224 under Other COC use (Pearl Index: 0.5; 95% CI: 0.4-0.5). Crude and fully adjusted (age, parity, current smoking, HC user status) Hazard Ratios for contraceptive failure of Qlaira compared to Other COCs were 0.4 (95% CI: 0.3-0.7) and 0.7 (95% CI: 0.4-1.0), respectively. Final results will be shown at ISPE.

**Conclusions:** The results do not suggest a higher risk of contraceptive failure in Qlaira users compared to users of other COCs.

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