



CARDIOVASCULAR SAFETY IN USERS OF DIFFERENT COMBINED ORAL CONTRACEPTIVES FINAL RESULTS FROM THE INAS-SCORE STUDY

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Background: A new combined oral contraceptive (COC) with a 26-day regimen containing estradiol valerate (EV) and dienogest (DNG), known as Qlaira (and Natazia in the US), was launched in 2009. It was unknown whether this new regimen and combination has an impact on the cardiovascular risk associated with the use of COCs.

Objectives: To investigate the cardiovascular long- and short-term safety of the estradiol valerate / dienogest (EV / DNG) containing COC (combined oral contraceptive) compared to established COCs.

Methods / Patients: Large, prospective, controlled, non-interventional cohort study with new users of different types of COCs: EV/DNG COCs and other COCs. It was conducted from 2009 to 2016 in the US as well as in Austria, France, Germany, Italy, UK, Poland and Sweden.

Interventions: non-interventional

Main Outcome Measures: Every 6 months during the first two years and yearly thereafter, the woman was contacted and specifically asked about hormonal contraceptive use and serious adverse events. All self-reported clinical outcomes of interest were validated by health care professionals. Main clinical outcomes of interest were venous thromboembolism and arterial thromboembolism. The analysis was based on logistic regression models. As requested by the European Medicinal Agency, final analyses are based on the European data only.

Results: Last interim analysis in September 2016 was based on 104,294 women-years (WY) of observation and 71,2952 WY of hormonal contraceptive exposure. Overall, 59 VTEs and 22 ATEs have occurred. For Qlaira, the VTE incidence was 6.7/10,000 WY and for Other COCs 7.3/10,000 WY. The crude HR for Qlaira vs. Other COCs is 0.9 (95% CI: 0.4-1.7). Adjustment for age, BMI, duration of current OC use and family history of VTE lead to an HR of 0.5 (95% CI: 0.2-1.0). The ATE incidence rate for Qlaira users was 0.7/10,000 WY; 3.5/10,000 WY (95% CI: 2.1 – 5.5) for 'Other COCs' and for LNG users 3.1/10,000 WY. Final results will be shown at ISPE.

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Conclusions: The results do not suggest a higher VTE or ATE risk of Qlaira users compared to users of Other COCs.