

OVALEAP® EFFECTIVENESS IN COMPARISON TO GONAL-f®: A POST-HOC ANALYSIS

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Abstract Body

Context: Ovaleap® (follitropin alfa), a biosimilar to Gonal-f®, demonstrated clinical equivalence in the pivotal phase 3 study, with comparable number of oocytes retrieved (primary endpoint). Some secondary endpoints showed not statistically significant variances between products. A post-hoc analysis was conducted to explore these variances as the original study did not.

Objective: To assess the relationship between the observed variances in some of the secondary endpoints of the phase 3 study and the effectiveness of Ovaleap® and Gonal-f®.

Method: Post-hoc analysis of the Ovaleap® phase 3 equivalence study, stratified by age (<30 years, 30-34 years, >34 years).

Patients: Infertile ovulating women, otherwise healthy, aged 18 to 37 years, with 2 normal ovaries and undergoing IVF or ICSI.

Interventions: Ovaleap® or Gonal-f®

Main Outcome Measures: Estradiol level on the hCG day; number of follicles > 14 mm; total r-hFSH dose; duration of FSH treatment; oocyte maturity; embryo quality; number of blastomeres per embryo transferred.

Results: The analysis included women receiving Ovaleap® or Gonal-f®: n = 32 and 33 (<30 years), 92 and 72 (30-34 years), and 25 and 35 (> 34 years), respectively. Compared to Gonal-f®, mean estradiol level on hCG day was lower for Ovaleap® in patients <30 years, similar in patients 30-34 years and higher in patients >34 years. Number of follicles >14 mm was slightly higher in Gonal-f® patients <30 and 30-34 years but higher in Ovaleap® patients >34 years. Total r-hFSH dose and days of therapy were lower in Ovaleap® patients <30 and 30-34 years, though lower in Gonal-f® patients >34 years. Oocyte maturity was similar across both treatments. Embryo quality was fairly constant with Ovaleap® independent of age, while Gonal-f® demonstrated slightly higher variability by age. The number of blastomeres per embryo transferred, distribution of the number of blastomeres, and dynamics of embryo growth, was similar in both treatments.

Conclusions: Ovaleap® is an established biosimilar to Gonal-f®. This post-hoc analysis confirms that the variances between the two products observed in the pivotal phase 3 study do not indicate different product effectiveness given the lack of consistency across the three age groups and thus are not clinically relevant.