



Gonal-f RFF vs. Gonal-f Multi-Dose for IVF Stimulation: A Prospective, Sequential Trial



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Objectives

Several previous studies have suggested efficiency differences for different formulations of Gonal-f. It has also been suggested that fill by mass technology should attenuate or eliminate these differences. This study was designed to compare the outcomes achieved with the use of Gonal-f multi-dose and Gonal-f RFF for IVF stimulation in normal responders.

Design

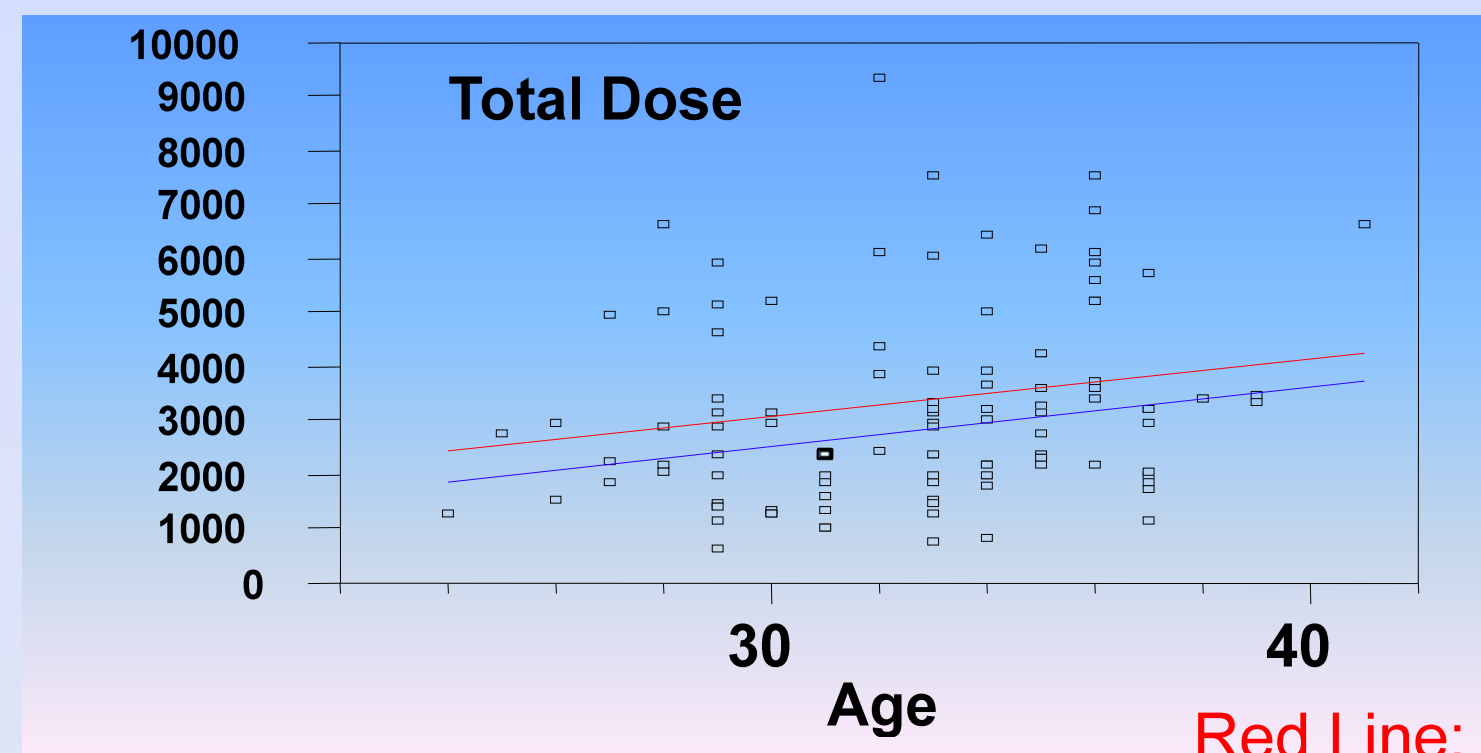
Sequential trial of two different formulations of recombinant FSH in a large private infertility practice.

Materials & Methods

109 normal responders undergoing IVF with Gonal F multidose or Gonal F-RFF were included in this trial. All patients were stimulated with our standard oral contraceptive/leuprolide acetate down-regulation protocol. R-hCG was administered when the largest follicle achieved a mean diameter of 20 mm, and transvaginal oocyte retrieval was performed 36 hours later. 57 patients were stimulated with Gonal F multidose (Group 1), while 52 received Gonal F-RFF (Group 2). Statistical analysis was performed using ANOVA, Wilcoxon sign-rank testing, and Chi Square analysis.

Results

There were no differences between the 2 groups in terms of patient age, days of stimulation, or starting FSH dose. Similarly, there were no differences in peak E2 levels, total number of oocytes retrieved, or number of embryos transferred. Group 2 patients required significantly less gonadotropin, they had more mature follicles on the day of hCG administration, and ongoing/delivered pregnancy rates were significantly greater in Group 2 as well.



Red Line: Gonal-f vial
Blue Line: Gonal-f RFF

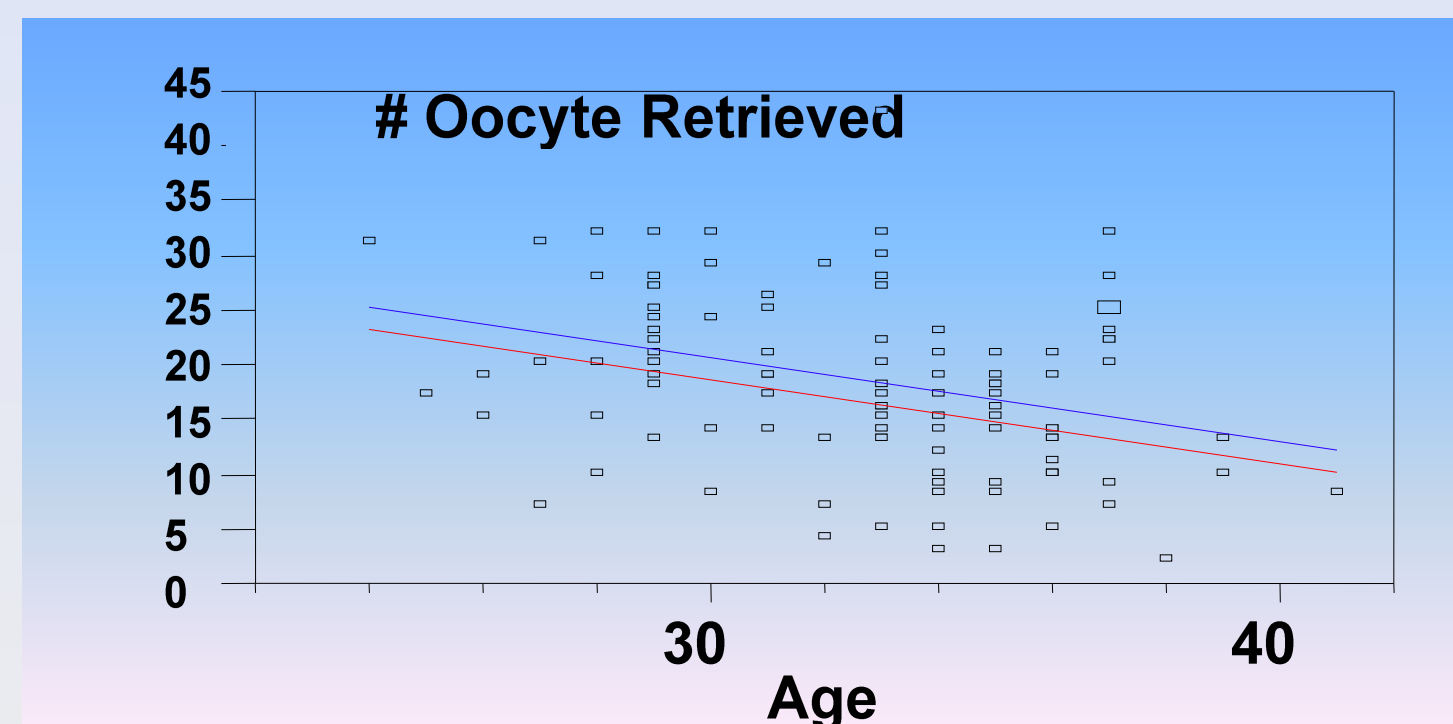


Table 1	Group 1 n=57	Group 2 n=52	P value
Patient Age (Years)	32.9	32.5	NS
Days of Stimulation	11.0	11.2	NS
Starting Dose (Units)	314.5	310.1	NS
Total FSH Dose (Units)	3407	2826	<0.05
Peak E2 (pg/mL)	2446	2902	NS
# Follicles > 15 mm	7.3	9.0	<0.05
# Oocytes Retrieved	16.5	18.8	NS
# Embryos Transferred	2.6	2.6	NS
Ongoing/Delivered Preg/ET (%)	45.6	71.1	<0.05

Conclusions

Gonal f-RFF appears to be more efficient than Gonal-f multidose, as Group 2 patients required significantly less gonadotropin to achieve follicular maturity than did patients in Group 1. In addition, Group 2 patients had significantly more mature follicles on the day of hCG administration. From a clinical perspective, both peak serum estradiol levels and the number of retrieved oocytes were significantly higher in Group 2 patients, although neither of these differences achieved statistical significance. Finally, Group 2 patients experienced significantly higher pregnancy rates. While this difference is more difficult to attribute to medication alone, based on the patient response to stimulation, it appears that Gonal F-RFF is more efficient than its predecessor.

Data analysis, Serono, Inc.