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## Clinical efficacy of hFSH versus rFSH for IVF: confirmatory results from the USA randomised trial.

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**Objective:** To compare the clinical efficacy of two subcutaneous FSH preparations (human FSH (Fostimon®, IBSA) versus r-FSH (Follitropin alpha) in volunteers undergoing controlled ovarian stimulation for in vitro fertilization.

**Design:** Prospective, investigator-blinded, randomized, controlled clinical trial conducted concurrently at four IVF centers in the United States.

**Materials and Methods:** Inclusion criteria were female age 18-39, BMI 18-30 kg/m<sup>2</sup>, basal FSH <10 IU/L and estradiol <80, >10 antral follicles (2-10 mm), normal uterine cavity, and fewer than 3 prior oocyte retrievals. Volunteers were randomized to human FSH (n=76) or to recombinant FSH (n=76) at a starting dose of 300 IU in down-regulated cycles. The gonadotropin dose could be increased or decreased after a minimum of two days of stimulation. Inferential statistics included intergroup comparisons of all study variables.

**Results:** There were no inter-group differences in any pre-treatment variables. The total IU of gonadotropin used did not differ between the two groups. There was no difference in number of oocytes retrieved, clinical pregnancy rate, live-birth rate with h-FSH compared with r-FSH. There were no differences in any objective measures of hyperstimulation and no volunteers required medical intervention for hyperstimulation.

**Conclusions:** In this study of good prognosis patients at a fixed starting dose of gonadotropin, there were no statistically significant differences in mean oocyte number, clinical pregnancy rate, or live-birth rate between human versus recombinant FSH.