The Use of Recombinant FSH in ART

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FSH is an essential folliculogenic hormone. Its use was popularised with urinary preparations, including highly purified products, from post-menopausal women. However, there can be much variation in activity related to the source at collection, and while this can be compromised to some degree in the purification, it adds to the variability in response and results. Since the first recombinant product was available for clinical trials in 1990, it is becoming evident that there are many advantages in its use. Because of its purity it is more acceptable to both physicians and patients, including the possibility of self-administration. We have used r-FSH (Gonal F, Serono) since 1997 in a down-regulation regime with good results. In a meta-analysis study of 12 clinical trials comparing rFSH with urinary FSH, Daya and Gunby ('99) concluded that the use of rFSH in assisted reproduction is preferred over uFSH. The common odds ratio and the risk difference (and their 95% confidence intervals), obtained by pooling the data using a fixed effects model, were 1.20 (1.02~1.42) and 3.7% (0.5~6.9%) respectively, in favour of rFSH. The pregnancy rate with the alpha preparation of rFSH was statistically significantly higher than with uFSH in IVF cycles. Out et al (1995) compared the use of rFSH and urinary FSH in 981 patients undergoing IVF and reported that patients treated with rFSH produced significantly more oocytes and embryos. In addition, the rFSH treatment group also required less gonadotrophin and a shorter treatment period compared to those given urinary FSH. Maximum serum estradiol levels were also significantly higher ($p<0.0001$) in the rFSH patient group. Although the on-going pregnancy rates per attempt and per transfer were not significantly different in either group; the cumulative pregnancy rates (i.e. including those from frozen thawed embryo replacement) were still significantly higher in those treated with rFSH ($p=0.05$). However with respect to the incidence of ovarian hyper stimulation syndrome, there were no significant differences between rFSH and urinary FSH. Bergh et al ('97) reported in the first comparative clinical study of Gonal-F vs uFSH (HP) that there was a significant improvement in oocytes retrieved (12.2 vs 7.6). Hoomans et al ('99) reported a significantly lower total dose was needed in the rFSH group (nearly 700 IU less) in a prospective study comparing with urinary FSH-HP, with similar results.

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