



## What's the principle for selecting u-FSH or r-FSH in ART: recent clinical evidences in women undergoing controlled ovarian stimulation for IntraCytoplasmic Sperm Injection (ICSI).

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Since 1980 gonadotrophins have been used in assisted reproduction programs to induce multifollicular growth and in the past decade the highly purified human urinary follicle stimulating hormones (u-hFSH) have been successfully adopted.

Since 1997, a new urinary FSH (Fostimon<sup>®</sup>, IBSA) has been made available in some European countries. This product is the result of a new purification ion-exchange chromatography column method. This preparation has a specific activity of <6000 IU/mg protein and a purity grade of <90%. These high levels of biological potency and safety allow Fostimon to be administered by both the intramuscular and subcutaneous routes.

In spite of their efficacy and safety clinically proven, more recently recombinant FSHs (rFSH) have been proposed as being safer and clinically advantageous over u-hFSH

In order to confirm the clinical efficacy and safety of u-hFSH (Fostimon<sup>®</sup> - IBSA) and r-FSH (Gonal-F<sup>®</sup>-Sero) both preparations given by subcutaneous route, a randomized study in women undergoing controlled ovarian stimulation for IntraCytoplasmic Sperm Injection (ICSI) has been carried out..

One-hundred and fifty patients aged 18-39 with normal basal FSH (< 10 IU) and body mass index <30 kg/m<sup>2</sup> were selected for the study. After a standard, long down-regulation protocol using GnRH analogues, patients were randomised to receive either Fostimon or Gonal-F at the initial dosage of 225 IU for 5 days. Then the dose was adjusted according to the ovarian response. Both drugs were administered by the subcutaneous route. The primary end-point was the total number of oocytes retrieved. The secondary end-points took into consideration the total dose of FSH (IU); the number of days of FSH stimulation and the duration of stimulation; the cancellation rate; the oestradiol serum concentration on the day of hCG injection; the number of follicles >14 mm on the day of hCG injection. Moreover, the oocyte quality was assessed including fertilization rate (Day 1); cleavage rate; blastocyst rate; number of mature oocytes (grade III-metaphase II) and of injected oocytes. The number of transferred and frozen embryos; the clinical pregnancy rate (per stimulated cycle, per oocyte retrieval and per embryo transfer) and the implantation rate, as well as the delivery rate and live birth rate per cycle, per oocyte retrieval and per clinical pregnancy has been compared between the two treatment groups.

Safety was evaluated by evaluation of adverse events occurring during the study (time of onset, severity, duration and action/treatment required); by the incidence of OHSS risk and by the assessment of the local tolerability at the injection site.