



Highly purified FSH and oocyte and embryo quality

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Objective:

To determine the effects of highly purified urofollitrophin, used for ovarian stimulation, on oocyte and embryo quality, as well as pregnancy and implantation rates.

Design:

Parallel randomised open-label clinical study.

Setting(s):

Parallel randomised open-label clinical study.

Materials and methods:

A total of 267 infertile couples undergoing an IVF/ICSI treatment. Women aged 18-38 years were included in this study if they fulfilled the following criteria: (i) infertility attributable to tubal factor, male factor or unexplained infertility; (ii) serum hormonal profile (FSH, LH, prolactin) within the normal range; (iii) regular ovulatory menstrual cycles of 25-35 days; (iv) presence of normal uterine cavity; (v) no treatment with gonadotrophins in the month prior to the study; (vi) first IVF treatment cycle; (vii) body mass index (BMI) ≥ 18 but ≤ 26 kg/m²; (viii) willingness to participate in the study and to comply with the procedures. Patients were excluded from this study if (i) they had an abnormal gynaecological condition/ disease; (ii) they had a previous poor response to gonadotrophins (used for intra-uterine insemination); (iii) they had a previous history of severe OHSS; (iv) they had polycystic ovarian syndrome (v) the male partner had azoospermia or clinical signs of infection detected in a semen analysis within 12 months prior to the treatment. A standard down-regulation protocol with GnRH analogue was applied to all studied couples. Highly purified urinary FSH (Fostimon, IBSA- Switzerland) was administered to 133 patients, while the remaining 134 patients, enrolled as a control group, were treated with recombinant FSH (Gonal-F, Serono-Italy). The primary endpoints studied were: number of morphologically mature oocytes retrieved, embryo quality, pregnancy and implantation rates. The secondary endpoints included were: total number of days of FSH stimulation, total dose of gonadotrophin administered, fertilization rate per retrieved oocytes, embryo cleavage rate, live birth and miscarriage rates, endometrial thickness and estradiol level on the day of hCG administration, cancellation rate, and incidence of moderate or severe OHSS.

Results:

Higher, though not statistically significant, pregnancy and implantation rates in the uFSH group versus the rFSH group were observed (46.5%-36.8% and 22.1%-15.8% respectively). There was evidence of a significantly higher Grade 1 embryo score ($p \leq 0.05$) in the uFSH group compared to the rFSH (42.1% versus 33.5%). Live birth rate was higher, though not statistically significant, in the uFSH group compared to the rFSH group.

Conclusion:

Highly purified uFSH (Fostimon) is as effective as recombinant FSH (Gonal-F) for ovarian stimulation in terms of oocyte and embryo quality, pregnancy and implantation rates.

