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Dong Hee Choi

Pochon CHA University College of Medicine, Korea

2002-present	Chief of Infertility section, Department of Ob/Gyn, Bundang CHA General Hospital
1997-present	Professor, Pochon CHA University College of Medicine
1985-2002	Staff, CHA General Hospital of Seoul
1982-1985	Residency at Severance Hospital, Yonsei University
1981	Graduated from College of Medicine, Yonsei University

Efficacy and Safety of LG Recombinant Human Follicle Stimulating Hormone (LBFS0101) Versus Follitropin Alpha (Gonal-F®) in *in vitro* Fertilization/Intracytoplasmic Sperm Injection Cycles: a Multi-center, Open, Randomized Comparative Clinical Trial

Dong Hee Choi[1], Tae Ki Yoon[2], Mi Kyung Koong[3]

[1]Bundang Cha General Hospital, [2]Cha General Hospital of Seoul, [3]Cheil General Hospital

Objectives: To compare the efficacy and safety of LG recombinant human FSH (LBFS0101) with follitropin alpha (Gonal F®) in women undergoing ovarian stimulation for *in-vitro* fertilization including intracytoplasmic sperm injection.

Design: multicenter, open label, randomized, parallel group, comparative phase III trial.

Setting: Three IVF centers

Patients: A total of 103 patients were enrolled between April 2005 and July 2005.

Intervention:

One hundred and three infertile women undergoing IVF-ET were entered into the study under the approval of the Institutional Review Board, and after informed consent. After down-regulation with buserelin acetate, patients were randomized to receive LBFS0101 (n=52; group I) or Gonal-F® (Serono Inc., Geneva, Switzerland, n=51; group II) for controlled ovarian hyperstimulation. Both recombinant human FSH (r-hFSH) were administrated at a starting dose of 150-300 IU per daily during the first 3~5 days, and then dosage of r-hFSH were adjusted according to the ovarian response.

Main outcome measures: The primary efficacy parameter was number of oocytes retrieved.

The secondary efficacy parameter were total dose of r-hFSH used and duration of stimulation, number of follicles more than 14 mm in diameter on the day of hCG, fertilization rate(%), implantation rate(%), clinical pregnancy rate(%), and E2 concentration on the day of hCG (pg/ml).

Safety was assessed as a secondary end point.

Results: After excluding 15 cancelled cycles, date from 88 cycles (LBFS0101=47 cycles; Gonal-F®= 41 cycles) were analysed. There were no statistically significant differences in clinical parameters of patients regarding age, body mass index, duration and cause of infertility, number of previous IVF cycles, and basal serum hormone profiles between two groups. And, the total dose of r-hFSH (2371.3 ± 728.4 IU for group I versus 2409.8 ± 769.4 IU for Group II; P=0.8314), duration of stimulation (9.3 ± 2.0 days versus 9.3 ± 1.8 days; P=0.6277), number of follicles of ≥ 14 mm on the day hCG injection (9.3 ± 4.6 days versus 10.6 ± 5.8;P=0.4620), and number of retrieved oocytes (14.2 ± 9.1 versus 14.4 ± 8.8) were not different between the two groups. Fertilization rate (79.3 ± 17.1% for group I and 79.8 ± 17.6% for group II; P=0.8973), clinical pregnancy rate (44.7% (21/47) versus 56.1%

(23/41); P=0.3442) and implantation rates (22.1% versus 29.5%) were similar in two study groups. Three cases of preclinical abortions (2 cases in group I and 1 case in group II)were noted, and 3 cases of tubal pregnancies (2 tubal pregnancies, and one heterotopic pregnancy) in Gonal-F® group were treated surgically. There were three cases (2.2%) of severe ovarian hyperstimulation syndrome in LBFS0101 group, and two (1.4%), in the Gonal- F® group. The incidence of adverse events, and injection site reactions were similar in both treatment groups. Anti-FSH antibody was not detected in any serum samples of all patients.

Conclusions: We found that new r-hFSH preparation (LBFS0101) is as effective as follitropin alpha (Gonal F®) in terms of number of oocytes retrieved, and clinical pregnancy rate in controlled ovarian hyperstimulation for *in vitro* fertilization-embryo transfer. And both treatments had a similar safety/ tolerability profile.