

Correction for: Efficacy and safety of recombinant human follicle-stimulating hormone in patients undergoing *in vitro* fertilization-embryo transfer

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This article has been corrected: The authors found several small errors and miscalculations, which were corrected making text consistent with the Supplemental Clinical Study Final Report:

Table 1. Baseline characteristics (MFAS population).

7th row: The unit “month” for the “Duration of infertility” was corrected to “year”, making it consistent with the Supplemental Clinical Study Final Report.

13th row: The *p*-value (0.242) for “Fertilization procedure, n (%)” was corrected to “0.212”. In addition, a footnote “b” (The total number of evaluable patients was 110 in the Gonal-F® Pen group)” was added.

RESULTS, Patients

The *p*-value in the last sentence in the **Patients** section was changed from *p* = 0.242 to *p* = 0.212.

Corrected sentence: “The distribution of the patients according to fertilization procedure was similar between the groups (*p* = 0.212).” This is now consistent with value in the corrected **Table 1**.

RESULTS, Efficacy – Primary outcome

In the first sentence of the “Primary outcome” section, the abbreviation “±SD” was corrected to “±SE”, and the number 13 was corrected to 13.5. This SE value was estimated from an ad hoc analysis for this manuscript; the analysis source (SAS output) is available. The number 13.5 was based on a result from the Clinical Study Final Report (Table 15, available).

Corrected sentence: “The least square mean (±SE) number of oocytes retrieved was 14.9 (± 0.5; median [range]: 14 [1 to 41]) in the Follitrope group and 12.8 (± 0.9; median [range]: 13.5 [3 to 33]) in the Gonal-F group, showing a treatment difference of 2.1 oocytes.”

RESULTS, Efficacy – Secondary outcome

A subtraction error was corrected in the following sentence, which changed 44.3% to 44.6%.

Corrected sentence: “In the Follitrope group, 186 patients (55.4%) underwent ET in contrast to 79 patients (71.8%) in the Gonal-F group; thus, the cancellation rate was 44.6% and 28.2% in the Follitrope and Gonal-F groups, respectively ($p = 0.0028$).”

A numerical error was also corrected in the following sentence, which changed 35.3% to 35.5%.

Corrected sentence: “The percentage of embryos that were successfully implanted in patients showing gestational sacs (i.e., implantation rate) was 39.8% in the Follitrope group and 35.5% in the Gonal-F group ($p = 0.376$).” This correction makes the stated numbers consistent with **Table 2**.

Table 2. Efficacy outcomes (PP population).

3rd and 4th rows: For “No. of follicles with diameter of ≥ 14 mm on hGC day” and “E2 concentration on hGC day, pg/mL), a footnote “a” was added based on the final result from the Clinical Study Final Report (Tables 26 and 36).

5th row: For “No. of oocytes retrieved” the footnote “c” (Values are mean \pm SE)” was added, as requested above for the “Primary outcome” section in the RESULTS. In addition, the p -value was corrected from “0.022” to “0.057” based on the final result from the Clinical Study Final Report (Table 16).

Corrected **Tables 1** and **2** are presented below.

Table 1. Baseline characteristics (MFAS population).

	Follitrope™ PFS (N = 336)	Gonal-F® Pen (N = 111)	<i>p</i> -value
Age, years ^a	29.4 \pm 3.9	29.3 \pm 3.6	0.814
Age, n (%)			0.376
20-30 yrs	198 (59)	73 (66)	
31-35 yrs	118 (35)	31 (28)	
36-39 yrs	20 (6)	7 (6)	
BMI, kg/m ^{2a}	21.4 \pm 2.7	21.3 \pm 2.6	0.881
Duration of infertility, year ^a	3.9 \pm 2.5	3.9 \pm 3.1	0.805
Main reason for infertility, n (%)			0.250
Tubal factor	149 (44.3)	42 (37.8)	
Male factor	105 (31.3)	46 (41.4)	
Unexplained	58 (17.3)	15 (13.5)	
Combined	24 (7.1)	8 (7.2)	
Fertilization procedure, n (%) ^b			0.212
IVF	182 (54.2)	50 (45.5)	
ICSI	130 (38.7)	53 (48.2)	
IVF and ICSI	24 (7.1)	7 (6.4)	
Basal FSH level, mIU/ml ^a	3.0 \pm 0.9	3.1 \pm 1.0	0.827
Basal E ₂ level, pg/mL ^a	21.4 \pm 12.4	20.4 \pm 10.6	0.498

^a Values are mean \pm SD

^b Total number of evaluable patients were 110 for Gonal-F® Pen group.

Table 2. Efficacy outcomes (PP population).

	Follitrope™ PFS (N = 336)	Gonal-F® Pen (N = 110)	p-value
Total injected dose of r-FSH, IU ^a	1945.3 ± 635.7	2020.2 ± 562.7	0.271
Duration of treatment, days ^a	10.7 ± 1.6	11.1 ± 1.4	0.027
No. of follicles with diameter of ≥14 mm on hCG day ^a	10.2 ± 4.0	10.1 ± 4.4	0.750
E ₂ concentration on hCG day, pg/mL ^a	4460.0 ± 2564.1	4051.9 ± 2583.5	0.167
No. of oocytes retrieved ^c	14.9 ± 0.5	12.8 ± 0.9	0.057
No. of Metaphase II oocytes, n (%) ^{a,b}	85.3 ± 14.0	85.0 ± 15.8	0.895
Fertilization rate (%)	70.6	74.6	0.079
No. of embryos transferred ^a	2.0 ± 0.3	2.0 ± 0.4	0.731
Embryo implantation rate (%)	39.8 (144/362)	35.5 (55/155)	0.376
Biochemical pregnancy rate (%)	4.3 (8/186)	10.1 (8/79)	0.110
Clinical pregnancy rate (%)	55.4 (103/186)	51.9 (41/79)	0.168
Ongoing pregnancy rate (%)	44.1 (82/186)	43.0 (34/79)	0.758

^a Values are mean±SD

^b ICSI patients only

^c Values are mean±SE