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NO DIFFERENCE IN CLINICAL OUTCOMES USING FOLLITROPIN ALFA (BIOSIMILAR) COMPARED TO FOLLITROPIN ALFA OR FOLLITROPIN BETA FOR CONTROLLED OVARIAN STIMULATION (COS) IN OOCYTE DONATION-RECIPIENT CYCLES.

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OBJECTIVE: To assess the safety and effectiveness of a recently available biosimilar follitropin alfa (Bemfola_) compared to established recombinant FSH preparations (follitropin alfa, Gonal-f_; follitropin beta, Puregon_) in an ART program.

DESIGN: Retrospective anonymized cohort analysis on all donor oocyte cycles using only r-hFSH for COS and clinical follow up data on recipient transfers carried out during 2016-2017

MATERIALS AND METHODS: In total, there were 2499 COS cycles in a donor population using different FSH preparations. Of these, 1547 were stimulated with FSH alone and of these, 1341 received r-hFSH for COS, of which 671 cases were with biosimilar follitropin alfa, 79 with follitropin alfa, and 591 with follitropin beta. Following a course of birth control pill or luteal phase oestradiol valerate, donors were stimulated from menstrual day 2-3 with daily r-hFSH (150-225 IU), with daily GnRH antagonist commenced from cycle day 6. Final follicular maturation was triggered using a GnRH agonist (0.2 mg) and oocytes were collected approximately 36 hours later. Oocytes were vitrified or fertilized in vitro and cultured to the blastocyst stage. Routinely one blastocyst was replaced in the recipient who was receiving hormone replacement to facilitate synchronization of the transfer procedure. Demographic, stimulation variables and pregnancy data were analysed using SPSS (Version 21.0). The main outcome measure was ongoing clinical pregnancy (week 12). Statistical analysis employed chi-squared with Pearson correction and logistic regression analysis for factors associated with ongoing pregnancy.

RESULTS: Overall mean donor and recipient age were 24.4 _ 4.4 and 41.3 _ 4.1 respectively. The total r-hFSH doses were 2014 _ 529, 1824 _ 559 and 2084 _ 677 for follitropin alfa, beta and biosimilar follitropin alfa respectively. ($p<0.05$ for the comparisons between follitropin beta vs both follitropin alfa preparations). The number of oocytes retrieved were 21 _ 10, 25 _ 11 and 26 _ 10 ($p<0.05$ for the comparisons between follitropin alfa vs its biosimilar and vs follitropin beta), resulting in a FSH dose per oocyte retrieved of 117 IU, 89 IU and 98 IU for follitropin alfa, beta and biosimilar follitropin alfa respectively ($p<0.05$ for all comparisons). The number of embryos transferred were: 1.5 _ 0.5 for follitropin alfa; 1.4 _ 0.5 for follitropin beta, and 1.3_0.5 for the biosimilar of follitropin alfa ($p<0.05$ for the comparison between follitropin alfa and its biosimilar). The ongoing clinical pregnancy rate in donor recipients was 52.8 % for biosimilar follitropin alfa (n¼ 579), 50.7%

(n¼73) for follitropin alfa and 51.3% for follitropin beta (n¼520) (p>0.05). All preparations were well tolerated at the site of injection.

CONCLUSIONS: This large retrospective study in a donor oocyte- recipient program demonstrates similar clinical efficacy for biosimilar follitropin alfa compared to established recombinant follitropins. References: "None" Supported by: This study was supported by an unrestricted educational grant from Preglem SA Switzerland