Major results of a phase III comparative multicenter study on the follitropin alfa biosimilar (Primapur®) and the original follitropin alfa (Gonal-f®)

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FULL TEXT:

PDF (RUS)

Abstract

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Abstract

A clinical study on the efficacy and safety of follitropin alfa has been conducted. The aim of the study was to confirm the therapeutic equivalence between the follitropin alfa biosimilar (Primapur®) and the reference medication (Gonal-f®) in controlled induction of superovulation within the assisted reproductive technologies (ART) programs. Materials and methods. This multicenter, randomized, blind at the embryological stage, in parallel groups, comparative study of phase III (RCT 754 from 26.10.16/NCT03088137) involved 110 women aged 20-35 years with established causes of infertility (tubal factor, male factor). The patients were randomized into 2 equal groups of 55 participants each. The primary end-point for assessing the therapeutic equivalence was the number of aspirated oocytes. The secondary end-points included the number of fertilized oocytes, the number of days of stimulation, the total dose of the injected drug, the occurrence rate of biochemical and clinical pregnancies. Results. In this study, the follitropin alfa biosimilar was shown to be equivalent to the original follitropin in terms of the number of aspirated oocytes. Also, no statistically significant differences were found in the number of mature and fertilized oocytes, the days of stimulation, the dose of the drug administered during the treatment, and the rate of the