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TITLE

USE OF BIOSIMILAR MEDICINES IN ART

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ABSTRACT

Context

Infertility afflicts 10% of the population. The most effective treatment is IVF. The drug used for controlled ovarian stimulation (COH) is urinary or recombinant follicle-stimulating hormone (FSH). Recombinant FSH (rFSH) is a biological medicine, recombinant version of the FSH grown in Chinese Hamster Ovary cells. rFSH is structurally closer to natural FSH and is more biopotent in vitro.

A biological medicine is derived from living cells and used in the medicine. The WHO defines a biosimilar as a biotherapeutic product similar in terms of quality, safety and efficacy to an already licensed reference biotherapeutic product. Unlike generics, biosimilars are similar to, but not identical copies of, the original biological. Biosimilars made by different manufacturers can differ from the original product and from each other.

Results

Safety and effectiveness studies should demonstrate that there are no significant differences in benefits or risks between original molecule and biosimilar.

Phase 1 study to compare pharmakinetics and to establish bioequivalence of biosimilar and reference medicine. Phase 3 study to evaluate efficacy, safety and tolerability of biosimilar compared to rFSH in women undergoing ART therapy.

European Medicines Agency (EMA) authorized FSH biosimilars. Phase III randomized controlled trials concluded that these products have been shown to have a comparable quality, safety and efficacy profile to reference product. As regard to the outcomes of ART procedures, in terms of oocytes retrieved and pregnancy rate, biosimilars seems to be not inferior to the originator product, but further studies are needed.

Conclusions

Recombinant human follicle stimulating hormone (r-FSH) is effective and safe for controlled ovarian stimulation but with elevated cost. Use of biosimilar products could substantially reduce the costs of ART treatments.

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