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Corifollitropin alfa (Elonva®) in Daily Clinical Practice

A Report from the IVF Institute "Das Kinderwunsch Institut" by Prim. Michael Schenk, MD, MAS

Recently, corifollitropin alfa (Elonva®) has become available to the IVF practitioners as an interesting and patient-friendly stimulation treatment option. We have adopted Elonva® in our internal treatment protocols in order to establish whether it represents a suitable therapy option for use at our Institute.

All observed clinical success parameters of our internal QM system have been fulfilled. Decreased patient discomfort due to fewer injections and patient-doctor consultation sessions proved advantageous to the patients. It is sustainably profitable for the Institute, not only directly by saving resources but also indirectly by increasing patient satisfaction.

Overview

Hormone therapy prior to egg collection (oocyte pick-up) for in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) is still the least patient-friendly part of the entire therapeutic protocol. Frequently, women with unwanted childlessness reject stimulation therapy that may consist of several daily injections. It may well be that this is the reason why many couples tend to seek professional help in fertility & reproductive medicine centres at a late stage (often too late).

The last two decades have sustainably revolutionized stimulation therapy. The introduction of the highly purified urinary FSH (highly purified human menopausal gonadotropin; HP-hMG), which allowed a switch from intramuscular to subcutaneous injection, brought the first advancement in this respect. The next significant breakthrough was the use of recombinant active substances that could be administered by a pen device. Furthermore, the option of using GnRH antagonists instead of the analogs significantly reduced the number of injections required and lowered the rate of side effects associated with the necessary inhibition of premature ovulation.

Corifollitropin alfa (Elonva®) is a recombinant FSH molecule displaying a uniform activity for 7 days. As part of the authorization process, international multi-centre studies ENGAGE [1] and ENSURE [2] delivered conclusive data, which established the suitable dose, confirmed a good safety profile, and validated equivalence with the results obtained upon ovarian stimulation with recombinant FSH.

One single injection of Elonva® can replace nearly the entire course of daily FSH injections in the stimulation protocol, which is an important step towards increased patient satisfaction.

Background

In order to establish whether Elonva® can prove of practical value to us and whether it meets the internal requirements of our quality management system, we closely followed the patients who received treatment at our Institute. We were particularly interested in establishing whether:

- Elonva® can deliver satisfactory pregnancy success rates, comparable to those obtained with standard stimulation methods used so far at our Institute; and
- whether the Institute's patients and clinicians regarded the Elonva® protocol as equally conductible and convenient as the standard methods employed to date.

In consultation with their treating clinicians, the patients with an established indication for IVF or ICSI have decided to undergo treatment with Elonva® at our Institute.

Our Protocol

We followed a fixed antagonist protocol and adhered to the Summary of Product Characteristics of Elonva®. Depending on the body weight, we administered either 100 micrograms or 150 micrograms of Elonva® on day 2 or 3 (100 mcg ≤ 60 kg; 150 mcg > 60 kg). We introduced the GnRH antagonist on day 5 of stimulation. The first vaginal ultrasound was performed on stimulation day 7 or 8, followed by stimulation with rFSH in the fixed dose of 150 IU (or 200 IU) until up to 3 follicles measuring ≥ 17 mm were found. Ovulation induction was performed with urinary hCG (5000 IU ≤ 80 kg; 10,000 IU > 80 kg).

If impending hyperstimulation was detected (defined as > 20 follicles measuring > 11 mm, or E_2 > 4500 pg/ml), ovulation was triggered with 0.2 mg of triptorelin and the embryos cryopreserved. The ovum pick-up (OPU; collection of oocytes from the follicles), IVF, ICSI, embryo transfer (ET), and luteal support were conducted in line with our in-house standard operating procedures (SOPs). In the case of positive hCG, additional ultrasound examinations were performed in the 7th week of gestation to verify the presence of fetal heart activity, as well as in the 13th week of gestation to establish an intact pregnancy.

Our observations

To date (July 2012), 69 patients received Elonva® at our Institute. Unlike the marketing authorization study protocols, treatment was made available to the patients up to the age of 42.

Stimulation experiences varied. At our Institute, Elonva® required 1.6 cycles per pregnancy. All embryological parameters such as the cumulus-oocyte complexes (COC), metaphase II (MII), fertilization rate, cleavage rate, the number of good-quality embryos on day 3, and the number of frozen embryos

were in line with our internal QM specifications safeguarding the lower and upper limits for the said parameters.

In 4 patients, we were able to prevent the ovulation hyperstimulation syndrome (OHSS) by administering triptorelin (Decapeptyl®) for ovulation induction. This was also below our internal 10 % warning limit for OHSS prevention.

The positive feedback collected from our patients referred to the significantly fewer injections required as well as fewer ultrasound examinations.

The entire team expressed satisfaction with the use of Elonva®. The initial apprehension associated with the possibly required weekend patient-doctor consultation sessions was circumvented by flexibility with respect to starting on either day 2 or 3 as well as by scheduling of the additional ultrasound examinations on day 7 or 8.

Our Conclusions

In our opinion, the use of Elonva® decreases the subjective burden of couples due to fewer injections and doctor-patient consultation sessions. The working conditions for the IVF laboratory staff were not compromised. Pregnancy rates were commensurate with our institutional specifications. The additional positive aspect was associated with reduced costs due to reduced staffing requirements and a more economical use of resources.

Our findings were presented at the annual meeting of the Austrian IVF Society in October 2012.

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