CONCLUSION: The availability of embryos for cryopreservation on day three is predictive of a higher likelihood of clinical and multiple PR. Specifically, our data suggests that transferring 2 embryos in patients aged 34 and 3 embryos in patients aged 34–39 who have embryos available for day three cryopreservation affords an excellent clinical PR while diminishing the risk of multiple pregnancy.

Supported by: None.

P-168

The routine use of a new formulation of follitropin alfa (FbM) for follicular development for IVF. A large multicenter observational study in the UK. E. McVeigh, A. Lass. John Radcliffe Hospital, Oxford, United Kingdom; Serono Ltd, London, United Kingdom.

OBJECTIVE: Until recently recombinant hFSH has been filled and released by bioactivity using in-vivo rat bioassay. The availability of an improved method of size exclusion highly precise liquid chromatography (SE-HPLC) enables the quantification of r-hFSH protein content filled by mass (FbM), in which 75IU FSH-activity corresponds to 5.5 mcg of r-hFSH protein. This new formulation of r-hFSH monodose also contains methionine. TWEEN, and 10% overfill that in combination provides more accurate and precise control over the actual dose delivered to the patient. So far in the UK only data from small controlled clinical trials has been published. In April 2003, the new formulation of Gonadof® FbM and a variety of new Gonadof® Multi-Dose preparations have been introduced in the UK and this is the first report on clinical experience of routine use of these products in normal IVF practice in the UK.

DESIGN: Non-interventional, post-marketing study

MATERIALS AND METHODS: Twenty-one IVF centres in the UK participated in this non-interventional post-marketing survey between April and December 2003. In total 1427 patients eligible for IVF were enrolled without either protocol or inclusion/exclusion criteria and each patient could be included only once in the survey. Treatment was according to normal clinical practice of each unit. The new formulation of Gonadof® FbM was available as a monodose vial of 75 IU and in new presentations including freeze-dried powder for solution in multidose vials of either 450 IU or 1050 IU. A short monitoring form was collected following the cycle, which included demographic and clinical performance data and nurses assessment.

RESULTS: Mean age of the patients was 34.3 years (range 20–48). Down regulation was attempted in 1255 (87.9%) cycles using the GnRh agonist and in 172 (12.1%) cycles by GnRh-antagonist. hCG was administered in 1001 (96.3%) of the cycles and oocyte retrieval was performed in 1384 (97.3%) cycles with a mean number of 10.3 oocytes retrieved. In 1213 (85.0%) cycles embryo transfer was performed with a single embryo-transfer in 103 (8.5%), 2-embryos in 945 (78.0%) and 3 embryos in 163 (13.5%) of the cycles. Positive hCG was recorded in 478 cycles (33.5% per ET). Sixty pregnancies (12.6%) resulted in spontaneous resolved miscarriage and one was an ectopic pregnancy. OHSS has been reported in 83 (5.8%) cycles, mostly mild and moderate while severe OHSS which resolved spontaneously has been recorded in 5 (0.4%) patients. Nurses trained most patients to handle the Multi-Dose preparation injections (97.4%) and nearly all patients (1280, 97.6%) viewed the dosing flexibility with the Multi-Dose as an advantage and simple procedure.

CONCLUSION: The routine use of the new formulation of Gonadof® FbM in monodose vials and the new Multi-Dose presentations in clinical practice in IVF has been demonstrated to be effective, safe and well received by patients delivering increased flexibility for adopting different controlled ovarian stimulation protocols for ART.

Supported by: Serono, Ltd.

P-169


OBJECTIVE: Adequate endometrial development is required for pregnancy to occur. Consequently, clinicians providing IVF for infertile couples must pay close attention to it. Assessment of the endometrium with ultrasound and/or histeroscopy was included. 16 of them received a single dose of GnRh antagonist (Cetrotide 3mg, Serono) for pituitary desensitization. 4 out of 16 underwent COH + IVF (Group Ia), 6 out of 16 underwent transfer of embryos from our oocyte donation program (Group IIa), and 6 out of 16 underwent transfer of frozen embryos (Group IIIa). Each group was compared to 16 patients who underwent the same IVF/ICSI procedures (Groups Ib,IIb,IIIb). These patients received GnRh agonist from the luteal phase of the previous cycle (Lupron, Abbot) until the day of the administration of hCG (Group Ib) or progesterone (Group IIb and IIIb) in the same period. Group I received gonadotrophin therapy (Gonal F, Serono) and groups II and III received increasing oral doses of micronized estradiol (Ronfase, Pharmacia). Endometrial thickness was evaluated by high resolution transvaginal ultrasound. We compared the endometrial growth rate within groups. Endometrial growth rate was calculated according to the formula ((late follicular phase endometrial thickness – baseline endometrial thickness)×100. We arbitrarily chose day 8 for baseline measurements and the day when hCG was indicated in Group I and day 15 in Groups II and III for late follicular phase measurements. Statistical analysis was performed by means of Student’s t test and Mann-Whitney Test. P < 0.05 was considered statistically significant.

RESULTS: There were no differences in the age of the patients in the three groups.

<table>
<thead>
<tr>
<th>Group</th>
<th>Endometrial growth rate</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ia</td>
<td>115.8 ± 144.8</td>
<td></td>
</tr>
<tr>
<td>Ib</td>
<td>37.0 ± 34.2</td>
<td>0.386</td>
</tr>
<tr>
<td>Ila</td>
<td>54.6 ± 19.5</td>
<td></td>
</tr>
<tr>
<td>IIb</td>
<td>23.7 ± 27.5</td>
<td>0.078</td>
</tr>
<tr>
<td>IIIb</td>
<td>57.0 ± 75.8</td>
<td></td>
</tr>
<tr>
<td>IIIb</td>
<td>51.0 ± 23.5</td>
<td>0.470</td>
</tr>
</tbody>
</table>

CONCLUSION: An association of various cycle characteristics and treatment outcome has been evaluated since the introduction of assisted reproduction technologies. One of these is endometrial thickness. In this preliminary study we did not find statistically significant differences between the patients treated with a single dose of GnRh antagonist and the patients who received our usual protocol as regards endometrial growth rate. It seems to be that this treatment does not exert a negative impact on endometrial thickness and could be another tool to make ART procedures easier for patients.

Supported by: None

P-170

Serum hCG concentrations in autologous and egg donation IVF cycles. S. Hotamisligil, R. Carson, S. Pang. Reproductive Science Center, Lexington, MA.

OBJECTIVE: To compare serum hCG concentrations measured on the twelfth day after embryo transfer (D12) in autologous IVF and recipients of donated oocytes.

DESIGN: D12 hCG concentrations in 577 women (younger than age 35) who had clinical pregnancies with autologous fresh embryo transfers between January 2001 and December 2003 were compared with D12 hCG concentrations of clinical pregnancies resulting from 68 egg donation cycles during the same time period.