Polycystic ovary syndrome. A therapeutic challenge

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Citation for published version (APA):
Appendix I

Characteristics of included studies

Study
Balasch et al., 2000

Methods
Randomised cross-over study, method of randomisation not stated. Duration and timing not stated. Single center study. No sample size with power calculation was performed. 22 patients randomised. Allocation concealment unclear. One pre- and one post-crossover cycle/patient. No intention-to-treat analysis performed. Source of funding not stated.

Participants
Women with oligo/amenorrhoea with ultrasonographic evidence of polycystic ovaries. Women had either failed to ovulate after clomiphene citrate treatment or had not conceived after a minimum of three ovulatory cycles at doses 200 mg/day for 5 days. Baseline characteristics for whole group only. Mean age (±SE) of the patients was 30.4 (0.9) years. Mean body mass index (SE) was 24.6 (0.5). Duration of infertility (SE) was 4.4 (1.3) years. Number of subjects with primary infertility was not given. The mean (SE) LH/FSH ratio was 2.5 (0.2).

Interventions
Chronic low dose step up regimen with two starting doses of recombinant FSH (Gonal-F® or Puregon®). Treatment was started at day 3 of an induced or spontaneous menses. Starting dose was 37.5 or 50 IU rFSH (sc)/day. The starting dose was maintained up to 14 days, unless follicle maturity was reached. If no ovarian response was noted after this period the dose was increased with 37.5 IU/d and 50 IU, respectively. Further dose adjustments after 7 days if necessary. HCG (10,000 IU, Profasi) was given when a follicle >17 mm developed. No cancel criteria stated.

Outcomes
Pre-crossover data available for ovulation and pregnancy rate only. For other outcomes pre- and post- crossover data were combined: total rFSH dose required, duration of stimulation, number of follicles >10-13, >13-14 and >17 mm on day of hCG, oestradiol concentration on day of hCG.

Notes
No definition of ovulation and pregnancy reported.