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human reproduction

SUPPLEMENTARY DATA

Supplementary Table SII Eligibility criteria.

Inclusion criteria	
1.	Informed consent documents signed prior to screening evaluations.
2.	In good physical and mental health in the judgement of the investigator.
3.	Asian pre-menopausal females between the ages of 20 and 40 years. The subjects must be at least 20 years (including the 20th birthday) when they sign the informed consent and no more than 40 years (up to the day before the 41st birthday) at the time of randomisation.
4.	Infertile women diagnosed with tubal infertility, unexplained infertility, endometriosis stage I/II (defined by the revised American Society for Reproductive Medicine [ASRM] classification, 1996) or with partners diagnosed with male factor infertility, eligible for IVF and/or ICSI using fresh or frozen ejaculated sperm from male partner or sperm donor.
5.	Infertility for at least 1 year before randomisation for subjects <35 years or for at least 6 months for subjects ≥ 35 years (not applicable in case of tubal or severe male factor infertility).
6.	The trial cycle will be the subject's first controlled ovarian stimulation cycle for IVF/ICSI.
7.	Regular menstrual cycles of 24–35 days (both inclusive), presumed to be ovulatory.
8.	Hysterosalpingography, hysteroscopy, saline infusion sonography or transvaginal ultrasound documenting a uterus consistent with expected normal function (e.g. no evidence of clinically interfering uterine fibroids defined as submucous or intramural fibroids larger than 3 cm in diameter, no polyps and no congenital structural abnormalities which are associated with a reduced chance of pregnancy) within 1 year prior to randomisation.
9.	Transvaginal ultrasound documenting presence and adequate visualisation of both ovaries, without evidence of significant abnormality (e.g. enlarged ovaries which would contraindicate the use of gonadotropins) and normal adnexa (e.g. no hydrosalpinx) within 1 year prior to randomisation. Both ovaries must be accessible for oocyte retrieval.
10.	Early follicular phase (cycle days 2–4) serum levels of FSH between 1 and 15 IU/l (results obtained within 3 months prior to randomisation).
11.	Negative serum Hepatitis B Surface Antigen (HBsAg), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) antibody tests within 2 years prior to randomisation.
12.	BMI between 17.5 and 32.0 kg/m^2 (both inclusive) at screening.
13.	Willing to accept transfer of 1–2 embryos.
Exclusion criteria	
1.	Known endometriosis stage III–IV (defined by the revised ASRM classification, 1996).
2.	One or more follicles ≥ 10 mm (including cysts) observed on the transvaginal ultrasound prior to randomisation on stimulation day 1 (puncture of cysts is allowed prior to randomisation).
3.	Known history of recurrent miscarriage (defined as 3 consecutive losses after ultrasound confirmation of pregnancy (excl. ectopic pregnancy) and before week 24 of pregnancy).
4.	Known abnormal karyotype of subject or of her partner/sperm donor, as applicable, depending on source of sperm used for insemination in this trial.
5.	Any known clinically significant systemic disease (e.g. insulin-dependent diabetes).
6.	Known inherited or acquired thrombophilia disease.
7.	Active arterial or venous thromboembolism or severe thrombophlebitis, or a history of these events.
8.	Known porphyria.
9.	Any known endocrine or metabolic abnormalities (pituitary, adrenal, pancreas, liver or kidney) with the exception of controlled thyroid function disease.
10.	Known presence of anti-FSH antibodies (based on the information available in the subject's medical records; i.e. not based on the anti-FSH antibody analyses conducted in the trial).
11.	Known tumours of the ovary, breast, uterus, adrenal gland, pituitary or hypothalamus which would contraindicate the use of gonadotropins.
12.	Known moderate or severe impairment of renal or hepatic function.

(continued)

Supplementary Table SII Continued

Exclusion criteria	
13.	Any abnormal finding of clinical chemistry, haematology or vital signs at screening which is clinically significant as judged by the investigator.
14.	Currently breast-feeding.
15.	Undiagnosed vaginal bleeding.
16.	Known abnormal cervical cytology of clinical significance observed within 3 years prior to randomisation (unless the clinical significance has been resolved).
17.	Findings at the gynaecological examination at screening which preclude gonadotropin stimulation or are associated with a reduced chance of pregnancy, e.g. congenital uterine abnormalities or retained intrauterine device.
18.	Pregnancy (negative urinary pregnancy tests must be documented at screening and prior to randomisation) or contraindication to pregnancy.
19.	Known current active pelvic inflammatory disease.
20.	Use of fertility modifiers during the last menstrual cycle before randomisation, including dehydroepiandrosterone (DHEA), metformin or cycle programming with oral contraceptives, progestogen or estrogen preparations.
21.	Use of hormonal preparations (except for thyroid medication) during the last menstrual cycle before randomisation.
22.	Known history of chemotherapy (except for gestational conditions) or radiotherapy.
23.	Current or past (1 year prior to randomisation) abuse of alcohol or drugs.
24.	Current (last month) intake of more than 14 units of alcohol per week.
25.	Current or past (3 months prior to randomisation) smoking habit of more than 10 cigarettes per day.
26.	Hypersensitivity to any active ingredient or excipients in the medicinal products used in the trial.
27.	Previous participation in the trial.
28.	Use of any non-registered investigational drugs during the last 3 months prior to randomisation.