Official Title
A Phase 3, Randomized, Double-blind, Active-controlled, Non-inferiority Trial to Investigate the Efficacy and Safety of a Single Injection of SCH 900962 (Corifollitropin Alfa) to Induce Multifollicular Development for Controlled Ovarian Stimulation (COS) Using Daily Recombinant FSH (recFSH) as a Reference in Women Aged 35 to 42 Years (Phase 3; Protocol No. P06029)

Purpose
The purpose of this study is to show that a single injection of SCH 900962 is non-inferior to daily injections of recFSH during the first week of ovarian stimulation in terms of the number of vital pregnancies (ie, presence of at least one fetus with heart activity as assessed by ultrasound at least 35 days after embryo transfer) in women aged 35 to 42 years undergoing controlled ovarian stimulation (COS) prior to in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI).

Sponsor: Schering-Plough
Est. Enrollment: 1400 subjects via 29 approved locations
Study Start Date: June 2010
Study Completion Date: June 2011

Eligibility
Ages: 35 Years to 42 Years  Genders: Female

Criteria
Inclusion Criteria:
• Willing and able to provide written informed consent for trial P06029 as well as for the Frozen-Thawed Embryo Transfer (FTET) follow-up trial P06031, and for the pharmacogenetic analysis (if applicable).
• Female and >=35 to <=42 years of age with indication for COS and IVF/ICSI.
• Body weight >=50.0 kg, BMI >=18.0 to <=32.0 kg/m2.
• Regular spontaneous menstrual cycle with variation not outside the 24-35 days
• Ejaculatory sperm must be available (donated and/or cryopreserved sperm is allowed).
• Results of clinical laboratory tests, cervical smear, physical examination within normal limits or clinically acceptable to the investigator.
• Adhere to trial schedule.

Exclusion Criteria:
• A recent history of/or any current endocrine abnormality.
• A history of ovarian hyper-response or ovarian hyperstimulation syndrome
• A history of/or current polycystic ovary syndrome.
• More than 20 basal antral follicles <11 mm (both ovaries combined) in the early follicular phase
• Less than 2 ovaries or any other ovarian abnormality
• Unilateral or bilateral hydrosalpinx
• Intrauterine fibroids >=5 cm or any clinically relevant pathology, which could impair embryo implantation or pregnancy continuation
• More than three unsuccessful COS cycles for IVF/ICSI since the last established ongoing pregnancy (if applicable)
• A history of non- or low ovarian response to FSH/hMG treatment
• A history of recurrent miscarriage
• FSH >15.0 IU/L or LH >12.0 IU/L during the early follicular phase
• Positive for HIV or Hepatitis B
• Contraindications for the use of gonadotropins or GnRH antagonists
• A recent history of/or current epilepsy, thrombophilia, diabetes, cardiovascular, gastro-intestinal, hepatic, renal or pulmonary or auto-immune disease requiring regular treatment
• Smoking or recently stopped smoking (ie, within the last 3 months prior to signing informed consent)
• A recent history or presence of alcohol or drug abuse
• The subject or the sperm donor has known gene defects, genetic abnormalities, or abnormal karyotyping, relevant for the current indication or for the health of the offspring.
• Prior or concomitant medications disallowed by protocol.

For more information, please visit ClinicalTrials.gov at: http://clinicaltrials.gov/ct2/show/NCT01144416?term=PURSUE&rank=1 or contact the Center’s study coordinator at:
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