

CURRENT RESEARCH STUDY

Gonal-F vs. Fostimon

Fertility Physicians of Northern California

Fertility Physicians of Northern California is participating in a multicenter in vitro fertilization (IVF) research study sponsored by Institut Biochimique SA (IBSA), makers of Fostimon®. Fostimon® is a purified Follicle Stimulation Hormone (FSH) preparation derived from human menopausal gonadotropins by a state of the art laboratory at IBSA. IBSA is an established pharmaceutical company in Switzerland.

The purpose of this research study is to compare a current FDA approved gonadotropin, Gonal-f™, to Fostimon®. Fostimon® is an approved and widely used drug in Europe. The study will assess the therapeutic efficacy, tolerance and safety of Fostimon®, the study medication, and compare it with that of Gonal-f™, the approved medication, using a subcutaneous injection route in female patients undergoing IVF.

You may be eligible to participate in this research study if you have been recommended by your physician to do IVF and have not done more than 2 prior cycles, are between the ages of 18-39, have normal uterine cavity documented by a hysterosalpingogram, hysteroscopy or sonohysteroscopy within one year of screening, normal screening lab values including day 3 Follicle Stimulating Hormone and Estradiol, and a desire to become pregnant. Semen analysis does not have to be normal.

You are not eligible to participate in this research study if you have been pregnant 3 months prior to screening, have done 3 or more cycles of assisted reproductive technologies (ART), have had prior ART failure related to fertilization or poor response to gonadotropins, or have a body mass index greater than 30.

The study protocol is similar to the standard IVF protocol used by the Fertility Physicians of Northern California, but may require extra visits to complete the study protocol. The dose for Fostimon® can be changed on day 3 of Fostimon® administration. If you choose to participate, you will benefit by receiving gonadotropin medication (Fostimon® or Gonal-f™) to complete an entire IVF cycle, at no charge to you. This represents approximately a \$2500 value. You will be responsible for the remainder of the charges for your IVF cycle.

Both drugs, study and approved, are known to be effective at stimulating ovarian follicular development. It is hypothesized (but not proven) that Fostimon® has an equivalent potency to Gonal-f™.

All Fertility Physicians of Northern California patients may choose standard IVF treatment and not participate in the research study.

If you are interested in participating in this research study, please contact:

Heather M. Rone, Clinical Research Coordinator
Fertility Physicians of Northern California
(408) 876-4766 **hrone@fpnc.com**