

# CURRENT RESEARCH STUDY

## Progesterone-IBSA vs. Endometrin®

### *Patient Participation Welcomed*

Fertility Physicians of Northern California is pleased to offer our patients the opportunity to enroll in a clinical trial comparing two progesterone formulations used for luteal support during in vitro fertilization (IVF).

Progesterone supplementation during IVF treatment increases delivery rates. Currently, IVF treatment employs progesterone given by deep injection or placed in the vagina. An experimental progesterone supplement, Progesterone-IBSA, is given by subcutaneous injection. Progesterone-IBSA has been used in Europe but not yet in the United States.

FPNC is one of eight clinics nationwide participating in a trial to compare this experimental progesterone, Progesterone-IBSA, which is administered subcutaneously, to an FDA approved progesterone, Endometrin®, which is administered vaginally. The study will assess the efficacy, tolerability and safety of Progesterone-IBSA in female patients undergoing IVF.

Dr. Karen Purcell, MD, PhD, FACOG is directing this study at FPNC. This research study is sponsored by Institut Biochimique SA (IBSA), an established pharmaceutical company in Switzerland.

You may be eligible to participate in this research study if you:

- have been recommended by your physician to do IVF
- have not done more than 2 prior IVF cycles
- are between the ages of 18-42
- have a normal uterine cavity
- have normal screening lab values
- have a body mass index of less than 30
- have at least 3 retrieved oocytes

You are not eligible to participate in this research study if you:

- have done 3 or more cycles of IVF
- have intramural uterine fibroids that distort the uterine cavity
- have endometrial polyps greater than 1 cm
- have Stage III or IV endometriosis
- plan to use thawed/donated oocytes or embryos

The study protocol is similar to the standard IVF protocol used by Fertility Physicians of Northern California, but may require extra visits to complete the study protocol. If you choose to participate, you will benefit by receiving progesterone medication (Endometrin® or Progesterone-IBSA) to complete an entire IVF cycle, at no charge to you. This represents approximately a \$1,036 value. Additionally, \$1500 will be given to each study participant for their time and commitment. You will be responsible for all other charges for your IVF cycle.

It is hypothesized (but not proven) that Progesterone-IBSA has an equivalent potency to Endometrin®

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



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

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