

CURRENT RESEARCH STUDY

Anastrozole vs. Clomiphene Citrate

Fertility Physicians of Northern California

Fertility Physicians of Northern California is participating in a multicenter ovulation induction research study, sponsored by Serono, Inc. This study will evaluate the safety and tolerability of anastrozole in women who do not ovulate regularly, by comparing it to clomiphene citrate, often known as Clomid® or Serophene®. It also aims to determine an effective dosage of anastrozole to induce ovulation in women who are experiencing infertility due to an inability to ovulate normally.

Anastrozole is a drug that is currently approved by the FDA in the United States for the treatment of breast cancer because it reduces circulating estrogen. Reducing circulating estrogen at the beginning of the menstrual cycle appears to stimulate the development and release of an egg. This is why we are investigating the use of anastrozole for ovulation induction.

You may be eligible to participate in this research study if you have been recommended by your physician to do an ovulation induction cycle, have not done more than 6 prior clomiphene citrate cycles and have never used gonadotropins. You must also be between the ages of 18 and 40, smoke no more than 4 cigarettes per day, have two fallopian tubes with two functional ovaries, have normal screening lab values including day 3 FSH and Estradiol, and a desire to become pregnant. Use of Metformin during the study is not allowed. Additional inclusion criteria will be evaluated by a physician. A semen analysis must also be within limits that are normal by the standards set for our laboratory. The use of donor sperm is not permitted in this study.

You are not eligible to participate in this research study if you have had more than 6 clomiphene citrate cycles in the past, three or more consecutive pregnancy losses due to any cause, have been clinically pregnant at any time within the 3 months prior to screening or have any medical condition which, in the judgment of the investigator and/or sponsor, may interfere with the menstrual cycle or absorption, distribution, metabolism or excretion of the study drug. Additional exclusion criteria will be evaluated by a physician.

The study protocol is similar to the standard ovulation induction protocol used by the Fertility Physicians of Northern California, but it may require extra visits to complete the study protocol. Participants will be randomly assigned either anastrozole in dosages of 1 or 5 mg for 5 days or clomiphene citrate in a dose of 50 mg for 5 days. If you choose to participate, pass the screening evaluation and sign the consent form, you will receive, at no cost, medication (anastrozole or clomiphene citrate), lab testing and ultrasound examinations for your ovulation induction cycle. You will also have the option to receive intrauterine insemination, with your partner's sperm, at no cost to you.

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

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

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