



OVULATION INDUCTION & SUPEROVULATION CONSENT FORM

During a natural menstrual cycle, hormones from the pituitary gland (LH and FSH) cause the growth of a fluid filled cavity, or follicle, within the ovary. Although several follicles start to grow each month, in a natural cycle, only one will become mature enough to ovulate its egg.

Fertility medications such as Clomiphene Citrate (Clomid), Letrozole (Femara) and gonadotropins (Gonal- F, Follistim, Menopur, Bravelle) are used to induce ovulation (if a patient is not already ovulating) or to induce superovulation which is to promote the release of more than one mature egg to increase the chances of conception. Another medication called the trigger shot (Ovidrel, Pregnyl) may be recommended to induce the release of a mature egg or eggs for better timing of intercourse or an intrauterine insemination.

Letrozole (Femara) is a medication that has been approved by the FDA for treatment of breast cancer. Its use as a fertility medication is “off label”. Letrozole is an aromatase inhibitor and it works by lowering the production of estrogen. Letrozole does not affect the cervical mucus or endometrial lining as much as Clomiphene citrate. The use of Letrozole has been associated with a possible increased risk of birth defects. However, several studies have refuted this claim.

Clomiphene Citrate (Clomid) is a selective estrogen receptor modulator. Although its chemical structure is similar to estrogen, Clomiphene Citrate is interpreted by the body as an anti-estrogen. This action “tricks” the pituitary into producing more FSH and LH which in turn stimulates the ovary to produce a follicle.

Risks of treatment with both Letrozole (Femara) and Clomiphene Citrate (Clomid) include but are not limited to failed cycle (no follicular development or no pregnancy), multiple pregnancy including higher order multiple pregnancy (triplets or more), cyst formation, a possible increased risk of cancer and birth defects, ovarian hyperstimulation syndrome, and an ectopic pregnancy.

The risk of a multiple pregnancy during ovulation induction is approximately 10% for those who conceive during the cycle with a twin gestation being most common. The risk of greater than twins is less than 1% for those who conceive in an ovulation induction cycle. The risk of a multiple gestation for those who conceive in a superovulation cycle is approximately 20% with a twin gestation being most common. The risk of greater than twins is less than 5% for those who conceive in a superovulation cycle. Pregnancies complicated by a multiple gestation are inherently more difficult pregnancies and are associated with many obstetrical complications and may be considered high risk. Selective reduction may be discussed by a high risk OB provider in the event of a higher order multiple pregnancy to reduce the gestation from a higher order multiple gestation to a twin or singleton gestation. There are risks associated with this procedure including loss of the entire pregnancy.

A definitive answer to whether or not fertility medications cause cancer is elusive as people have different risk factors, studies have methodological limitations and the incidence of these cancers is low. In a practice guideline for fertility specialist, the American Society of Reproductive Medicine concludes that given the available data, patients should be counseled that infertile women may be at an increased risk of invasive ovarian, endometrial and breast cancer; however, use of fertility medications does not appear to increase these risks. However, this remains a debated issue.

The risk of birth defects in the general population is 2%-3% and is slightly higher amount infertile patients. Most of this risk is due to delayed conception and the underlying cause of infertility. Whether fertility treatments alone are responsible for birth defects remains under debate and study. There may also be an increased risk of miscarriage with the use of fertility medications but this may be explained by closer monitoring for pregnancy in this patient population.

A condition call Ovarian Hyperstimulation Syndrome (OHSS) is extremely rare with the use of oral fertility medication such a Clomid and Femara. It is more often associated with use of gonadotropins. In this condition, the ovaries significantly enlarge accompanied by abdominal swelling, abdominal pain, nausea and vomiting, fluid accumulation in the abdomen and lungs. Hospitalization and drainage of fluid from the abdomen may be required if severe.

As a result of treatment, an ectopic pregnancy may result which is a pregnancy implanted outside of the uterine cavity and is often located in a fallopian tube. The risk of an ectopic pregnancy is slightly higher with the use of fertility medications than when a pregnancy is conceived without any treatment. An ectopic pregnancy can not be saved and can be life threatening. Treatment is indicated and under certain circumstances, a medical treatment can be utilized. However, occasionally, an ectopic pregnancy will require surgical intervention which may result in removal of the involved fallopian tube.

Occasionally, it may be necessary to cancel a treatment cycle following its initiation due to either a poor response to the medication or an overly vigorous response with the development of too many follicles presenting an unacceptable risk of a higher order multiple pregnancy. In this situation, the trigger shot will be withheld and you will be asked to abstain from sexual intercourse until the start of your next period. It may also be recommended that you take medication to interfere with implantation.

Side effects of Letrozole (Femara) and Clomiphene Citrate (Clomid) include hot flashes (10 to 20%), ovarian cyst formation, fatigue, joint and muscle pain, ovarian enlargement and abdominal pain, breast tenderness, headaches, bloating, nausea, and mood swings. Visual changes are rare but should be reported to Dr. Faber and the medication discontinued.

I understand and accept the risks of ovulation induction or superovulation infertility treatment and give my consent to proceed with this treatment. I have been given the opportunity to ask questions and all my questions have been addressed to my satisfaction.

Patient's Signature

Date

Husband's (Partner's) Signature

Date

Witness Signature

Date