

CONSENT FOR CONTROLLED OVARIAN HYPERSTIMULATION

Controlled ovarian hyperstimulation (COH) is the process by which a woman's ovaries are stimulated with fertility medications to induce the growth of multiple eggs. Several fertility treatments rely on COH as an inherent part of the treatment to improve the likelihood of conception. When combined with intercourse or with intrauterine insemination (IUI), COH increases pregnancy rates by leading to the growth and release of multiple eggs from the ovaries simultaneously. In egg freezing and in vitro fertilization (IVF) cycles, COH plays an integral part in allowing for the growth and harvesting of multiple eggs from the ovaries.

Typically, COH is performed with the use of daily injectable hormones (called gonadotropins) administered over the course of 7-10 days. Occasionally, COH is achieved with intermittent use of injectable hormones combined with orally administered medications. During COH, vaginal ultrasound examinations and blood tests will be performed periodically every several days to monitor the growth of ovarian follicles (containing eggs).

Potential Risks of Controlled Ovarian Hyperstimulation:

Discomfort at the injection site: The risk associated with daily injection of medications and with occasional blood drawing is for the most part limited to temporary mild pain or discomfort at the injection (or phlebotomy) site, and possible formation of a mild hematoma (bruise), which tend to spontaneously resolve over a short course of time.

Emotional or psychological changes: The Medications which you will be using are hormones, which may elicit an emotional response. The response varies from individual to individual but may include depression, euphoria, restlessness, irritability, and sleeplessness. For a full description of the side effects of all of the medications, you are encouraged to ask for the package insert.

Ovarian hyperstimulation syndrome: All medications which stimulate follicle growth in the ovaries may produce a condition known as "ovarian hyperstimulation syndrome (OHSS)." In these instances, the ovaries over-respond to the medications, become cystic and grow to a large size, and there is often an associated accumulation of fluid in the abdomen ("ascites"). Patients with OHSS may become nauseous and feel bloated. In severe cases, patients may experience significant shortness of breath and pain due to fluid accumulation, which may require the evacuation of fluid from the abdominal cavity. In extreme cases admission to the hospital may be required in order to give intravenous fluids and for pain management and observation. The incidence of severe OHSS is approximately 1% and a moderate form is expected in about 5% of cases. Very rarely OHSS has been associated with blood clot formation in the lungs, heart, kidneys and brain, and with death. Rarely, ovarian cysts may rupture leading to pelvic pain and internal bleeding, which may require surgical intervention.

Ovarian torsion: Since COH induces the growth of multiple follicles (containing eggs) within one or both ovaries, ovaries have a tendency to enlarge beyond their normal size. Rarely, an enlarged ovary may undergo twisting called ovarian torsion. Ovaries may undergo torsion spontaneously after COH or following physical activity which may lead to significant movement of the pelvic organs (aerobic exercise like jogging/running, jumping, cycling, and any other activity involving acute hip flexion/extension). As ovaries may remain enlarged and cystic for several weeks even after ovulation induction or egg retrieval, the risk of ovarian torsion will persist until ovaries regain their normal size. Therefore, it is important to limit strenuous physical activity like aerobic exercise for a minimum of two weeks following ovulation or egg retrieval. When ovarian torsion occurs, moderate to severe pelvic pain is often experienced on one or both sides of the lower abdomen, as well as occasional nausea/vomiting and low-grade fever. If ovarian torsion is suspected surgical intervention is often necessary to "untwist" the ovary in order to alleviate pain and other symptoms and to prevent permanent damage to the ovary. The likelihood of ovarian torsion following COH is extremely low (<1%).

Multiple gestation: All types of COH treatments may increase the risk for multiple gestation (twins, triplets, quadruplets, etc.). These are inherently difficult pregnancies, which may be further complicated by underlying health problems or age. Conditions associated with multiple gestations may include, but are not limited to: premature labor, premature birth, stillbirth (death of one or more of the fetuses), incompetent cervix, gestational diabetes, pregnancy-induced hypertension, placenta previa and blood clots. Cesarean section is commonly required to deliver these babies safely, and at a much higher incidence than what is normally seen for singletons.

Predicting or preventing a patient from experiencing any of these events once the pregnancy has been established is extremely difficult. Women who conceive a higher-order multiple gestation (triplets or more) will be offered the option of have selective fetal reduction, a procedure in which one or more fetuses is “reduced” for the purpose of prolonging the gestation and lowering the risk for prematurity and other complications. A selective fetal reduction procedure carries with it a small risk (3-4%) of complete miscarriage.

Ectopic pregnancy: COH may increase the risk of an ectopic pregnancy (a pregnancy located outside of the uterus, most often in the fallopian tube). An ectopic pregnancy cannot be saved and must be terminated. If an ectopic pregnancy is diagnosed, under certain conditions, medical treatment can be given to terminate the pregnancy. Occasionally, an ectopic pregnancy will require surgical intervention, which may result in removal of one of the fallopian tubes.

Cycle cancellation or other options: Occasionally it may be necessary to cancel a COH cycle following its initiation. This may result from either a poor response to the medication or an overly vigorous response. In patients undergoing COH with timed intercourse or IUI, in the event of a strong ovarian response due to fertility medications, proceeding with treatment (by taking a trigger shot to release the eggs from the ovaries) may significantly increase the risk for a multiple gestation and/or OHSS. In the event that the risk for a multiple gestation and/or OHSS is high, patients are presented with the option of canceling the cycle to significantly lower such risks, or converting the cycle to an in vitro fertilization (IVF) cycle, thereby creating embryos for embryo transfer or for future use.

Cancer: Some studies have suggested an association between fertility drugs and ovarian and breast cancer. This association has been challenged by many fertility specialists in the United States and abroad. Most research studies have failed to demonstrate any causation between the use of fertility medications and ovarian or breast cancer. Additionally, COH does not seem to be associated with increased risk of endometrial or cervical cancer.

Initials

Certification of Informed Consent for Controlled Ovarian Hyperstimulation

Your signature below indicates that you have read the preceding consent, that you have had the opportunity to ask questions, and that your questions have been answered to your satisfaction.

PATIENT NAME (PRINT)

PATIENT SIGNATURE

DATE

PARTNER NAME (print)

PARTNER SIGNATURE

DATE

WITNESS (print)

WITNESS SIGNATURE

DATE