

Informed Consent for Use of Aromatase Inhibitors (AI) for Infertility Treatment

Reproductive Care Center

My physician has recommended the use of an aromatase inhibitor such as Letrozole (common available brand name Femara) for ovulation induction or enhancement. My husband and I understand that aromatase inhibitors (AI) are currently only FDA approved for decreasing the risk of recurrence of breast cancer. The drug manufacturer does not support the use of Femara for infertility treatment. However, we understand that research has shown that these agents may be beneficial in some cases of infertility. They can be particularly helpful for assistance in inducing ovulation. We understand that Aromatase inhibitor medications work by blocking the enzyme conversion of androgenic hormones to estrogenic hormones, thereby lowering levels of estrogen in the body. This therapy minimizes the number of eggs released during ovulation induction. This is especially important in women with polycystic ovarian syndrome (PCOS) who tend to release multiple eggs with ovulation induction. These drugs do not seem to have some of the adverse side-effects such as decreased cervical mucus, thinning of the endometrial lining or emotional irritability that are common with the use of clomiphene citrate. The incidence of twins is 2-3% with the use of Femara compared to 10% with the use of clomiphene. The addition of FSH injections to either of these medications can increase the risk of multiples.

However, we understand AI agents may be harmful to a developing baby, especially if taken while the wife is pregnant, and they should therefore not be taken while she is pregnant. In order to be sure that she is not pregnant, we understand that she should have a pregnancy test each cycle before beginning these medications. Preliminary data (abstract presented at the American Fertility Society Meeting in Montreal in October 2005) suggested the incidence of birth defects in babies born after the use of Femara was approximately 4.7% (based on approximately 150 babies born). Although this is higher than what was seen in the control group that was used in this small study, this rate of birth defects is not significantly different from the anticipated rate of 3-4% in the general population. A more recent study suggests that the incidence of birth defects may be as low as 2.4% (based on more than 500 babies born), which is certainly not different than the normal population (Fertil. Steril. 2006;doi:10.1016/j.fertnstert.2006.03.014). The rate of malformations in the clomiphene citrate group was 4.8%. Further research is warranted in order to confirm that AI agents are safe.

We also understand that these agents have not been used for fertility therapy for a longtime, and there may be more risks, which are not currently known. We acknowledge that they have not yet been approved by the FDA for use in infertility treatment. We understand that if the wife uses these medications for treatment of infertility, we do so with full knowledge that she should not be pregnant while taking these medications, and it is our responsibility to be tested to be sure she is not pregnant before taking these medications. Furthermore, we understand that her use of these medications may not benefit in the way anticipated and may cause adverse effects, which were not anticipated.

We have had the possible benefits and risks of Aromatase inhibitor medications explained to us and we have had the opportunity to have all our questions answered. It is our desire to use these medications with a full understanding that the benefits may not be greater than the risks. We accept full responsibility to be sure the wife is not pregnant while taking them, and for any potential adverse results of taking these medications while pregnant or trying to get pregnant.

Wife's Signature

Date

Husband's Signature

Date:

Witness Signature

Date: