BRAVERMAN
IVF & Reproductive Immunology, P.C.
Answers for Recurrent Pregnancy Loss

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Consent to Assisted Reproductive Procedures: Ovarian Stimulation, Collection and Preparation of Semen, Intrauterine Insemination (IUI)

It has been determined through diagnostic testing and /or previous infertility treatments that we are candidates for assisted reproductive procedures. We understand that assisted reproductive procedures are not always successful and that alternative therapies may be available to us. We have considered the available options and elect to pursue this treatment.

Procedures:

1. Diagnostic tests, such as semen analysis, blood tests to determine baseline hormone levels, PAP test, vaginal cultures and ultrasound examination of the ovary to determine baseline follicle count may be performed prior to initiating treatment.

2. Oral contraceptive pills containing estrogen and progesterone may be taken in the menstrual cycle immediately prior to the intrauterine insemination (IUI) treatment cycle to induce a baseline state for the ovaries. A synthetic hormone medication called Lupron may be taken by subcutaneous injection to temporarily suppress the pituitary gland from stimulating the ovaries. Medications containing ovarian stimulating hormones (FSH, LH, hCG) may be taken by subcutaneous injection to stimulate the growth of several ovarian follicles containing eggs.

3. Periodic blood tests will be performed to monitor the changes in hormone levels related to the growth of the ovarian follicles that contain the egg(s). Blood samples will be kept for approximately one week and then discarded.

4. Ultrasound examinations will be used to monitor the growth of the ovarian follicles and to determine when the follicles reach maturity. Ultrasonography is a diagnostic procedure that uses sound waves to provide a picture of the ovaries. Upon reaching maturity, a medication containing the hormone hCG will be taken by subcutaneous injection to induce the final maturation and ovulation of the eggs.

5. A semen specimen from the partner will be obtained by masturbation in a room specially designed for this purpose and processed to isolate the best sperm for fertilization.

6. The prepared sperm will be concentrated into a small volume of specially formulated culture medium and drawn up into a small plastic tube (catheter). The catheter will be passed through the cervix into the uterus and the sperm will be deposited in the uterine cavity. Sperm deemed unsuitable for insemination (dead sperm, sperm with poor motility, etc.) are discarded immediately after insemination

7. Progesterone supplements, in the form of vaginal suppositories, will be used in the early stages of pregnancy to maintain and promote the continuation of the pregnancy.

8. A blood sample will be taken approximately 7 days after the insemination to assess the progesterone level and make sure it is adequate to support a pregnancy. A blood sample will be taken approximately 14 days after insemination to determine whether pregnancy has occurred and is proceeding normally.

9. If a pregnancy is initiated, twice-weekly blood tests and weekly ultrasound examinations will be performed to monitor the ongoing pregnancy The patient is transferred to the care of an obstetrician at 12 weeks of pregnancy.

Risks:

1. Blood Sampling - Frequent blood sampling can cause discomfort and bruising at the site of venipuncture.

2. Ultrasound Examination - There are currently no known risks associated with ultrasound examination of the ovaries.

3. Semen Collection - There are currently no known risks associated with producing a semen specimen by masturbation.

4. Medications - Several medications are used before and during the ovarian stimulation and to maintain an ongoing pregnancy. Any medication can cause side effects and the medications associated with infertility treatment are no exception. However, major side effects are very rare.

   Oral Contraceptive Pills (Desogen, etc.)
   This medication is a low dose estrogen/progesterone pill taken during menstrual cycle prior to initiating ovarian stimulation in order to induce a quiescent, baseline hormonal state and to prevent the development of ovarian cysts. The potential risks associated with long term exposure to oral contraceptive pills include, but are not limited to, the following: development of blood clots, heart attack, stroke, gall bladder disease and very rarely, liver tumors. Since exposure to this medication will be brief (21 days), the potential risks are very low. Side effects may include vaginal bleeding, fluid retention, spotty darkening of the skin, nausea and vomiting, change in appetite, headache, nervousness, depression, dizziness, loss of scalp hair, rash and vaginal infections.

   Leuprolide Acetate (Lupron for subcutaneous injection)
   This medication is a synthetic hormone that temporarily stops the body from producing other hormones that stimulate the ovaries. When the medication is stopped, hormone levels will return to normal. This medication may cause side effects that include, but are not limited to: nausea, vomiting, hot flashes, night sweats, bone pain, swelling of feet and ankles, headache or difficulty urinating. These symptoms usually disappear as the body adjusts to the medication.

   Menotropins (Pergonal, Gonal F, Follistim, Repronex, etc., for subcutaneous injection)
   These medications (follicle stimulating hormone and luteinizing hormone) are used to stimulate the growth of ovarian follicles and induce ovulation. These medications may cause side effects that include, but are not limited to: fever, breathing trouble, bloating, stomach pain or upset, enlarged ovaries, irritation at the site of injection and/or skin rash. These symptoms usually regress without treatment in two to three weeks after egg retrieval. Ovarian Hyperstimulation Syndrome (OHSS) is distinct from enlarged ovaries and is characterized by an increase in vascular permeability that results in the rapid accumulation of fluid in the peritoneal cavity, thorax and potentially, the pericardium. Early symptoms of OHSS include severe pelvic pain, severe bloating, nausea, vomiting and rapid weight gain. OHSS occurs in 0.4- 1.3% of women taking menotropins. Any patient experiencing

symptoms of OHSS should immediately contact the clinical staff at 212-750-3330.

Chorionic Gonadotropins (hCG, Profasi, Pregnyl, Ovidrel, etc. for subcutaneous injection)
This medication (hormone) is used to induce the final maturation of the eggs and ovulation. This medication may cause side effects that include, but are not limited to: headache, stomach pain, irritability, restlessness, mood changes, fatigue, acne and pain or irritation at the injection site.

Progesterone (for intramuscular injection or suppository)
This medication (progesterone hormone) is used to maintain the appropriate hormonal balance after the egg retrieval to maximize the possibility of implantation and continued pregnancy. This medication can cause side effects including, but not limited to, the following: nausea, headache, depression, itching, increased hair growth, increased sensitivity to sunlight, changes in menstrual flow, increased vaginal secretions, breast tenderness, fluid retention and pain or irritation at the injection site.

5. Intrauterine insemination - The intrauterine insemination is a non-surgical procedure that carries the slight risk of infection. The intrauterine insemination procedure is usually painless or only causes minimal discomfort. The procedure usually takes approximately ten minutes to complete.

6. Multiple Gestations - Because multiple eggs are ovulated and more than one egg may fertilize following intrauterine insemination, multiple gestations (twins, triplets or more) may result. This may increase the risk of premature delivery and other maternal complications and increase financial and emotional cost. Pre-term delivery may also result in complications to the offspring including long-term disabilities or death. Selective Fetal Reduction (termination of the growth of one or more fetuses) is an available alternative, with its own attendant risks and benefits.

7. Pregnancy - If pregnancy is successfully established, there is still a possibility of miscarriage, ectopic (tubal) pregnancy, stillbirth and/or congenital abnormalities (birth defects). At this time, the risk of the development of an abnormal fetus is not believed to be greater than in a natural; y conceived pregnancy. In the event that any serious abnormality is discovered, the various alternative courses of action, including elective termination of pregnancy, will be outlined ar,d discussed, with the final decision on the course of action residing with the patient. The program's statistical experience in achieving pregnancies has been explained. There is no guarantee that this procedure will result in a successful pregnancy.

8. Psychological Stress - Infertility treatment is an emotionally difficult process to go through. The relative uncertainty of treatment outcome can result in considerable anxiety. Counseling is available for those couples who feel they would benefit from talking with a professional trained in the specific issues associated with infertility.

Consent

1. We understand that certain diagnostic tests such as semen analysis, blood tests, and ultrasound examination of the ovaries may be performed in preparation for an intrauterine insemination procedure at Braverman Reproductive Immunology P.C. and that these tests carry associated risks. We certify these risks have been explained to us and we hereby consent to participate in these diagnostic tests.

2. We understand that there are risks associated with taking fertility enhancing medications, and although at the present time no conclusive evidence exists that these medications increase the risks of breast, ovarian, or other cancers, we do understand that future studies may modify the

above statement. We acknowledge the risks have been explained to us and we hereby consent to use these medications.

3. We understand that certain therapeutic procedures such semen preparation and intrauterine insemination will be performed in conjunction with my treatment at Braverman Reproductive Immunology P.C. and that these procedures carry associated risks. I certify that these risks have been explained to us and we hereby consent to participate in these procedures.

4. We understand that multiple eggs will be ovulated and sperm from my partner will be introduced into the uterus to achieve fertilization. If multiple eggs fertilize, and if the embryos develop appropriately, more than one embryo may implant in my uterus. We understand that there is a significant risk of high order multiple gestation (triplets, quadruplets and more) associated with intrauterine insemination. We hereby certify that the risks associated with these procedures have been explained to us and that we hereby consent to participate in these procedures as part our treatment at Braverman Reproductive Immunology P.C..

5. We understand that the reasonably known risks and consequences associated with intrauterine insemination include a slight chance of infection. After the insemination, blood tests will be required to monitor hormone levels and to determine if pregnancy has occurred. In addition, if pregnancy does result, additional blood tests and ultrasound examinations will be required to monitor the ongoing pregnancy. We understand that as with any pregnancy, there is a risk of complication during the pregnancy and childbirth. These include, but are not limited to the following:
    a. ectopic (tubal) pregnancy
    b. multiple gestation
    c. infection
    d. hemorrhage
    e. cesarean section
    f. all of the customary risks associated with carrying a child and giving birth

6. We understand that if a pregnancy occurs, it is important to obtain appropriate prenatal medical care and we agree to do so. We understand that our failure to obtain such care may adversely affect the pregnancy and / or the fetus and agree to seek appropriate prenatal care.

7. We understand that that there is no guarantee that we will become pregnant as a result of the intrauterine insemination procedure at Braverman Reproductive Immunology P.C.. Any of the following conditions may occur which would prevent the establishment of pregnancy:
    a. The response to the ovary stimulating medications may be poor and the insemination may be cancelled
    b. The egg(s) may not be mature or of sufficient quality to fertilize.
    c. In some cases, the partner may be unable to supply a semen specimen.
    d. Fertilization may not occur.
    e, The embryo(s) may not develop normally.
    f. Implantation of the embryo(s) into the wall of the uterus may not occur.

8. We understand that we are free to discontinue participation in the intrauterine insemination program at Braverman Reproductive Immunology P.C. at any time, by informing the staff either verbally or in writing. We understand that our decision to discontinue participation will in no way prejudice other treatment that we may receive from the staff at Braverman Reproductive Immunology P.C..

CONSENT FOR OVARIAN STIMULATION COLLECTION/PREP SEMEN, IUI

9. We understand that should the results of my treatment or any aspect of it be published in medical or scientific journals, all possible precautions will be taken to protect our anonymity. We grant permission to Braverman Reproductive Immunology P.C. to publish information relating to my case in professional journals, providing that our names are not used.

10. We understand and acknowledge that the staff at Braverman Reproductive Immunology P.C. has not undertaken hereby, or in any other document or oral communication, to advise us of our legal rights, now existing or hereafter arising, and specifically disclaim any responsibility to do so. We understand that Braverman Reproductive Immunology P.C. recommends that we seek legal counsel so as to be fully informed of our legal rights and obligations, but if we elect not to do so, such election is hereby acknowledged to have been determined without reliance upon statements, oral or written of Braverman Reproductive Immunology P.C.

11. We confirm that the exact nature of intrauterine insemination and associated procedures, together with the known risks of the procedures, have been explained to us by our treating physician in the consultations leading up to the signing of this document. We understand the explanation that has been given and have had the opportunity to ask any questions and to have these questions answered. Any future questions we have may be addressed to the staff of Braverman Reproductive Immunology P.C. We acknowledge that these procedures are being performed at our request and with our consent.

12. We confirm that we are:
    - ☐ married to each other and are sexually intimate partners.
    - ☐ not married and we are sexually intimate partners.

13. We attest that we are not married to anybody else.

Patient's Name	Signature	Date
Partner's Name	Signature	Date
Clinic Witness's Name	Signature	Date