BRAVERMAN
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Answers for Recurrent Pregnancy Loss

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Consent to Assisted Reproductive Procedures: Thaw and Transfer Cryopreserved Embryos

Purpose of the Embryo Cryopreservation Program

Embryo cryopreservation is the process whereby pre-implantation stage embryos, deemed to have good developmental potential, are frozen under strictly controlled conditions and then stored in a frozen state with the express purpose of maintaining their developmental potential for a future date. When desired, embryos are thawed under strictly controlled conditions, assessed for viability, and, if deemed to have good developmental potential, are transferred to the hormonally prepared uterus.

Medical Procedures

1. Diagnostic tests, such as blood tests to determine baseline hormone levels and infectious disease screening, PAP test, vaginal cultures and ultrasound examination of the uterus and a "mock" embryo transfer may be performed prior to initiating treatment.
2. Oral contraceptive pills containing estrogen and progesterone will be taken in the menstrual cycle immediately prior to the donor embryo treatment cycle to induce a baseline state for the ovaries. A synthetic hormone medication called Lupron will be taken by subcutaneous injection to temporarily suppress the pituitary gland from stimulating the ovaries. Transdermal skin patches containing estrogen will be worn to stimulate the growth of inner lining of the uterus (endometrium).
3. Periodic blood tests will be performed to monitor the changes in hormone levels related to the growth of the endometrium. Blood samples will be kept for approximately one week and then discarded.
4. Ultrasound examinations will be used to monitor the growth of the endometrium and to determine when the endometrium is in a physiological state appropriate to receive the embryos. Ultra-sonography is a diagnostic procedure that uses sound waves to provide a picture of the uterus.
5. Some or all of the cryopreserved embryos will be thawed under strictly controlled conditions approximately 1-3 hours prior to the embryo transfer. Embryos will be assessed for viability and only those embryos deemed viable and to have good developmental potential will be considered for transfer to the uterus. Prior to transfer, "assisted hatching" will be performed. The developing embryo is contained within a protein coat. At the blastocyst stage, the embryo must "hatch" out of this protein coat in order to make direct cell-to-cell contact with the lining of the uterus and facilitate implantation. Embryos that have been frozen and thawed can experience difficulty "hatching" out of this protein coat. Accordingly, a procedure known as "assisted hatching" is routinely performed prior to embryo transfer. Assisted hatching is a' technique that involves making a small hole in the protein coat of the developing embryo to facilitate the hatching process. This procedure has been in clinical use for more than 10 years and there have been no reports indicating that this procedure increases the incidence of miscarriage or birth defects.
6. Usually three, but occasionally more or less, frozen - thawed embryos are transferred to the uterus. The embryo(s) are deposited at the top of the uterine cavity using a small, flexible plastic tube

(catheter). The embryo(s) must initiate attachment to the endometrium and continue the implantation process in order for a successful pregnancy to occur.

7. Progesterone supplements 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 14 days after transfer to determine whether pregnancy has occurred and is proceeding normally.
9. If a pregnancy is initiated, blood tests and ultrasound examinations will be performed to monitor the going pregnancy.

Risks:
The potential risk or discomforts of in vitro fertilization and related procedures include, but are not limited to the following:

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 uterus.
3. PAP Test - There is a slight risk of temporary vaginal bleeding associated with the sampling the surface of the cervix.
4. Vaginal Cultures - There is a slight risk of temporary vaginal bleeding associated with the sampling the surface of the cervix.
5. Mock Embryo Transfer - In preparation of the actual embryo transfer performed following in vitro fertilization of the eggs and subsequent embryonic development, a "mock" or "trial" embryo transfer may be performed in a preceding cycle to determine the depth of the uterine cavity and the curvature of the cervical canal. The "mock" or "trial" embryo transfer is a non-surgical procedure that is usually painless or causes only minimal discomfort. The "mock" embryo transfer carries a slight risk of infection. The procedure usually takes approximately ten minutes to complete.
6. Medications - Several medications are used during ovarian stimulation, embryo transfer and to maintain an ongoing pregnancy. Each of the medications has potential side effects as follows:

   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.

Estrogen (Estradiol Transdermal Patches or pills)
This medication (estrogen 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: dizziness, headache, lightheadedness, stomach upset, bloating and nausea. These symptoms usually disappear as the body adjusts to the medication.

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.

Muscle Relaxant (Valium Tablets)
This medication is used to relax the pelvic muscles immediately prior to the embryo transfer. This medication can cause side effects including, but not limited to, the following: stomach upset, blurred vision, headache, confusion, depression, impaired coordination, change in heart rate, trembling, weakness, memory loss, dreaming or nightmares. The symptoms usually disappear in a matter of hours as the medication wears off.

Antibiotics (Doxycycline Capsules)
This medication is used to prevent infection following egg retrieval. This medication can cause side effects including, but not limited to, the following: stomach upset, diarrhea, nausea, headache, vomiting and increased sensitivity to sunlight.

Corticosteroids (Medrol Tablets)
This medication is used to slightly suppress the immune system and thereby enhance embryo implantation. This medication can cause side effects including, but not limited to, the following: dizziness, nausea, indigestion, increased appetite, and weight gain, weakness or sleep disturbances. These effects usually disappear as the body adjusts to the medication.

4. Embryo Transfer - An embryo transfer is a procedure not requiring anesthesia that carries the slight risk of infection. The embryo transfer procedure is usually painless or only causes minimal discomfort. The procedure usually takes approximately ten minutes to complete.

5. Multiple Gestations - 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. Multi-fetal reduction (termination of one or more embryos) is an available alternative, with its own attendant risks and benefits.

6. 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 naturally 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 and 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.

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

Consent

1. I / We understand that certain diagnostic tests such as blood tests, ultrasound examination of the uterus and a mock embryo transfer may be performed in preparation for transfer of thawed embryos at Braverman IVF & Reproductive Immunology P.C. and that these tests carry associated risks. I / We certify these risks have been explained to me/us and I / We hereby consent to participate in these diagnostic tests.
2. I / We understand that certain therapeutic procedures such as embryo thawing and embryo transfer will be performed in conjunction with my treatment at Braverman IVF & Reproductive Immunology P.C. and that these procedures carry associated risks. I certify that these risks have been explained to me and I / We hereby consent to participate in these procedures.
3. I / We understand that the reasonably known risks and consequences associated with the transfer of frozen - thawed embryo(s) to my uterus include a slight chance of infection. After the embryo transfer, 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. I / 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 the risks and inconveniences associated with carrying a child and giving birth.
4. I / We understand that if pregnancy occurs that it is important to obtain appropriate prenatal medical care and I / we agree to do so. I / We understand that my/our failure to obtain such care may adversely affect the pregnancy and / or the fetus and agree to seek appropriate prenatal care.
5. I / We understand that that there is no guarantee that I will become pregnant as a result of the transfer of thawed embryos. Any of the following conditions may occur which would prevent the establishment of pregnancy:
    a. My endometrium does reach an adequate physiological state to support a pregnancy
    b. The embryo(s) may not survive the freezing and thawing procedure.
    c. Implantation of the embryo(s) into the wall of the uterus may not occur.
6. I / We understand that I / We am / are free to discontinue the embryo thaw treatment cycle at Braverman IVF & Reproductive Immunology P.C. at any time, by informing the staff either verbally or in writing. I / We understand that my/our decision to discontinue participation will in no way prejudice other treatment that I / We may receive from the staff at Braverman IVF & Reproductive Immunology P.C..
7. I / We understand that, in accordance with the Fertility Clinic Success Rate Act of 1993, all fertility clinics are required by federal law to report annually birth outcomes for the purpose of delivery validation and as a tool to measure and assess any potential long term affects of assisted reproductive techniques on patients and their offspring. You will be asked to provide this program

with information regarding your pregnancy, labor and delivery, and birth outcome. The data that you and/or your obstetrician provide will be collected and reported anonymously with the highest regard for preserving your confidentiality. Data from your ART procedure will also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on you, CDC applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Service Act, Section 308(d). This means that any information that CDC has that identifies you will not be disclosed to anyone else without your consent.

8. I / We understand that should the results of my / our treatment or any aspect of it be published in medical or scientific journals, all possible precautions will be taken to protect my/our anonymity. I / We grant permission to Braverman IVF & Reproductive Immunology P.C. to publish information relating to my case in professional journals, providing that my name is not used.
9. I / We understand and acknowledge that the staff at Braverman IVF & Reproductive Immunology P.C. has not undertaken hereby, or in any other document or oral communication, to advise me/us of my legal rights, now existing or hereafter arising, and specifically disclaim any responsibility to do so. I understand that- Braverman IVF & Reproductive Immunology P.C. recommends that I / we consult legal counsel so as to be fully informed of my/our legal rights and obligations, but if I / we elect not to do so, such election is hereby acknowledged to have been determined without reliance upon statements, oral or written of Braverman IVF & Reproductive Immunology P.C..
10. I / We confirm that the exact nature of thawing and transferring cryopreserved embryos and associated procedures, together with the known risks of the procedures, have been explained to me / us by our treating physician. I / 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 IVF & Reproductive Immunology P.C. I / We acknowledge that these procedures are being performed at our request and with our consent.

Patient's Name	Signature	Date
Partner's Name	Signature	Date
Witness's Name and Title	Signature	Date

Patient Initials_____