



SPAR · SPECIAL PROGRAM OF ASSISTED REPRODUCTION

A Program of the Bedford Research Foundation Clinical Laboratory

Massachusetts 501(c)(3) not for profit organization

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Infertility Procedures & Clinic Collaboration

Methods of conception available to SPAR patients, as well as information about Bedford's collaboration with infertility centers world wide.

SPAR Infertility Procedures

Specimens collected through SPAR are currently tested for use in two methods of conception: in vitro fertilization (IVF) and Oligospermia Cup (Milex). Specimens are not prepared for use in intrauterine insemination (IUI) procedures because it is the opinion of the Centers for Disease Control and Prevention that IUI with sperm from an HIV infected male has not been proven safe, and because Bedford scientists have concerns about the possibility of rare, undetected HIV-infected cells being placed directly into the uterus.

It is important to remember that SPAR is designed as a clinical trial. The current protocol calls for sperm cryopreserved from two specimens with an undetectable viral burden for each conception attempt, and for the female partner to have herself tested for HIV-antibody at 3 weeks, 3 months, and 6 months following each and every pregnancy attempt.

In Vitro Fertilization

Because IVF does not involve direct contact between the mother and the sperm, it is considered by some to be the safest approach to conception, although this is not known with certainty.

As with all IVF procedures, the woman is given medication to regulate her cycle and cause her ovaries to mature more than one egg. While on medication, she will be monitored with blood tests and ultrasound exams. Just prior to ovulation, an egg collection will be performed under anesthesia as a day surgery procedure. The eggs are removed from her ovaries and combined with tested sperm in a culture dish in the laboratory. For this process, many clinics prefer to use a method termed intra-cytoplasmic sperm injection (ICSI). This method involves selecting a single sperm with a small glass needle and then inserting the sperm into the egg. In this way, each egg is exposed to only one sperm.

If the eggs are successfully fertilized; they will be returned to the woman's uterus within the next several days.

Additional patient information is available from the American Society for Reproductive Medicine at: www.asrm.org.

Cervical Cup Insemination (Oligospermia Cup)

Started in 2001, this is a newer SPAR procedure. Women (generally under the age of 36) with no fertility problems may undergo an Oligospermia Cup procedure if the tested specimens have a relatively high sperm count.

An oligospermia cup is a modified cervical cap that was developed many years ago by Milex. At the exact time an egg is released from the ovary, a physician will place the cup over the cervix and fill it with the thawed, tested sperm.

The sperm swim through the cervix into the uterus, thus avoiding the entry of other cells, and bypassing

the concerns about depositing HIV-infected cells directly into the uterus. However, because of the direct exposure to sperm, the woman takes one dose of anti-retroviral drugs (usually AZT) at the time of insemination. The medication is probably not necessary, but one dose of AZT is considered harmless to the pregnancy and may provide peace of mind.

The cup will remain in place not more than four hours. To maximize the possibility of achieving a pregnancy, it is important that the physician monitor the woman's ovary for a few days in order to pinpoint the exact time an egg will be released (ovulation).

The monitoring involves measurement of hormones in the blood along with ultrasound examinations of the ovaries. The advantages of this procedure over IVF are lower costs, avoidance of multiple hormone injections, and decreased risk of twins and triplets. This procedure is not recommended for couples with low sperm counts or women over 37.

For more information about the oligospermia cup:

<http://www.milexproducts.com/products/fertility/>

The Bedford Research Foundation's clinical laboratory is a not for profit, Massachusetts public charity. The laboratory operates on the principle that revenues and information from existing laboratory tests should be used to support research and the development of new tests.

Collaborating Fertility Centers

Bedford Research Foundation offers semen testing services to infertility centers willing to assist couples with an HIV infected male and an uninfected female.

Our goal is to help couples find fertility treatment close to their homes. We have a growing, national network, currently 26 collaborating fertility centers. During your initial consultation with Dr. Kiessling, she will discuss which centers might work best for you or will advise you on the best method for approaching the doctor of your choice. Patient and clinic confidentiality is strictly observed.

Risks

The risk of the mother or baby contracting HIV disease from this procedure is less than it would be if a pregnancy were attempted by using unprotected sex or sperm from untested specimens. As of July 2007, no one using tested semen has become infected.

The risks of the infertility procedures

Because of the controversial nature of the program, we do not release the names of collaborating clinics until you are formally in the program. You are welcome to speak with any local infertility clinic or reproductive endocrinologist to ask for help. We would be happy to work with anyone in your area. We strongly advise you to discuss your needs for confidentiality about your HIV diagnosis at the initial contact for fertility treatment.

Contact the Foundation (email, fax and phone info below), with the name of the referring physician

themselves will be explained by the gynecologists and infertility specialists.

Although no one has become infected following the use of tested sperm, the SPAR protocol includes HIV antibody testing at 3 weeks, 3 months and 6 months after each and every pregnancy attempt.

In general, pregnancy success depends upon the clinic. As of August, 2007, 67 babies have been born from all procedures, with all moms and babies testing negative for HIV disease.

and/or clinic. Alternatively, the clinical coordinator or physician may contact the Foundation directly. Patient and clinic confidentiality is strictly observed.

Infertility Procedure Costs

Costs vary according to the clinic. The cup insemination procedure costs about \$2,000 to \$3,000 per attempt in Boston; IVF is \$8,000 to \$15,000. You need to make arrangements with the clinic in advance.

How Do I Begin?

Return the *History Questionnaire* and *Consult Request* form with payment. The SPAR Coordinator will call you to schedule a consult.

Dr. Ann Kiessling will review your specific circumstances, the risks associated with the procedures, the treatment options available for you, and answer your questions.

She will be your advocate with fertility clinics and your infectious disease physician, if necessary. Should your semen analyses be problematic, she will recommend urologists or fertility specialists who can help you.

Pregnancies and Births

The Special Program of Assisted Reproduction (SPAR) started in 1994 as a support group for couples living with incurable sexually transmitted virus diseases such as AIDS. Baby Ryan, the first SPAR baby, was born May 1999.

Pregnancies and Births as of August, 2007:

- 72 pregnancies have been achieved through SPAR and IVF, procedures, 8 are ongoing.
- 9 pregnancies and 7 births have been achieved using the Oligospermia Cup procedure, 2 are ongoing.
- 67 babies have been born using SPAR:
12 sets of twins and 43 singlets.

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