

Intracytoplasmic Sperm Injection Consent

INTRODUCTION

This information is part of the informed consent process. It should give you the basic idea of what Intracytoplasmic Sperm Injection (ICSI) procedures are and what participation will involve. If you would like more details about something mentioned here please ask your Heartland Fertility & Gynecology Clinic (Heartland) physician. Please read this information carefully.

ICSI is an optional procedure used during In Vitro Fertilization (IVF). IVF involves removing oocytes (eggs) from the ovaries, fertilizing them in the laboratory, and replacing a specific number of the embryos that develop into the uterus in an attempt to initiate a pregnancy. IVF was originally developed in 1978 to help couples in which the woman's tubes were blocked, removed or diseased to the point that a pregnancy could not occur. IVF can also be used for the treatment of couples with unexplained infertility, endometriosis and in those who have severe male factor infertility. The standard method of insemination for IVF is done with about 100,000 sperm placed with every 5 eggs in a culture dish. When the sperm are from a man with a normal sperm count and the sperm are normal in appearance, an average of 60% of the eggs will fertilize normally.

However, in men with a low sperm count or motility, or abnormal looking sperm, the likelihood that the eggs will fertilize will be much lower, depending upon the quality of the original sperm sample. ICSI is an alternate method of insemination used during the IVF procedure to allow couples with a very poor semen analysis to achieve fertilization and pregnancy.

This method of fertilization is also indicated in couples that have previously done an IVF cycle in which no fertilization occurred.

ICSI is a microsurgical fertilization technique used since 1992. It is performed under a microscope by selecting a single sperm and injecting it directly into an egg. As only one sperm is required to for each egg, this allows for the treatment of couples that have a very low sperm count. Their sperm can be collected either by masturbation, microsurgical epididymal sperm aspiration (MESA) or testicular sperm extraction (TESE). At Heartland an average of

approximately 60% of all eggs injected are successfully fertilized, a similar rate to standard IVF insemination with sperm with normal parameters. Eggs that have not matured cannot be injected. Injecting a sperm into an egg does not guarantee it to fertilize or to continue development.

The remaining steps with ICSI are the same as for the standard IVF procedure. The number of embryos to be replaced in the uterus is individualized based on the appearance of the embryos, the age of the female partner and other factors. Suitable excess embryos can be cryopreserved in liquid nitrogen and stored for future use.

Advantages and Disadvantages of Intracytoplasmic Sperm Injection

ICSI allows some infertile couples the possibility of achieving a pregnancy that otherwise could not. Before ICSI, severe male factor infertility was seldom treated successfully and the recommendation was to use donor sperm.

ICSI is a complex and invasive procedure requiring the female partner to undergo in vitro fertilization. During the ICSI process it is possible that the egg could be damaged by the fertilization attempt. At Heartland, the ICSI fertilization rate is very similar to the fertilization rate of standard IVF insemination (average 60%). The ongoing pregnancy rate after a single cycle of IVF with ICSI is approximately 30%.

There is a concern that the ICSI procedure may allow males that previously could not have biological children to pass on their abnormal sperm traits to their male offspring. This question may not be fully answered for at least another 10 years. With respect to the infants that have already been born as a result of the procedure, there does not appear to be an increased risk of major and minor congenital abnormalities when compared to babies that are born after natural conception. However, there is concern that there may be a higher incidence of some genetic abnormalities in these infants.

Initial research suggests that there is a 1 to 2% increase in the number of sex chromosome abnormalities in these infants. For that reason, couples that achieve a pregnancy through ICSI will have the option of having an amniocentesis to try to detect such an abnormality. We now know that there are an increased number of genetic abnormalities in men with very severe sperm abnormalities. Potentially these genetic defects could be passed on to their children. Men who wish to undertake ICSI have the option of having genetic testing prior to undertaking IVF with ICSI.

ICSI is relatively new and therefore there is no long-term data of children born as a result of this technology. As they grow older, follow-up is continuing. Early research on children born after IVF/ICSI seems to indicate a small increased risk of being affected by chromosomal abnormalities and male offspring may have future fertility problems. Couples wishing to proceed with IVF/ICSI accept these small risks.

Alternatives to ICSI

From the above description it is evident that ICSI is a complex procedure that can be costly. For couples that are comfortable with the options of donor insemination this less expensive option may be preferred. The treatment of artificial insemination with therapeutic donor sperm (TDI) is also available at Heartland.

Couples with a short period of infertility may elect to give spontaneous conception a prolonged period of time to achieve their goals before enrolling in the IVF/ICSI program.

IN SIGNING THIS CONSENT, WE ACKNOWLEDGE THAT WE HAVE READ AND UNDERSTAND THE ACCOMPANYING INFORMATION. WE AGREE TO SOME OR ALL OF THE EGGS RETRIEVED BEING TREATED BY INTRACYTOPLASMIC SPERM INJECTION (ICSI). WE UNDERSTAND THAT:

1. Not enough sperm may be available to treat every egg.
2. Some eggs may not be suitable for treatment with ICSI. Eggs that are immature cannot be injected.
3. Of those eggs treated with ICSI, not every egg will fertilize, and some may fertilize abnormally.
4. Some of the eggs may be damaged during the injection process, and may not survive.
5. Not all embryos will develop normally. Abnormal embryos are not suitable for transfer.
6. If more embryos develop normally than are required for replacement into the uterus, suitable excess embryos can be frozen. Cryopreserved embryos may not survive the freeze or thaw process.
7. There is no guarantee that pregnancy will result from these procedures. The possibility of having a baby with an abnormality exists as it does for natural conception. In addition, early research suggests there is small increased risk of having a baby with genetic abnormality. Couples achieving a pregnancy through ICSI will be offered an amniocentesis.

DATED on this _____ day of _____, _____

FEMALE SIGNATURE

PARTNER SIGNATURE

WITNESS

WITNESS

I have consulted with and explained the contents of this Consent Form to the patient and her partner.

DATE

PHYSICIAN SIGNATURE