Sperm Selection by Microfluidic Separation Improves Embryo Quality

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UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Sperm Selection by Microfluidic Separation Improves Embryo Quality

This is a clinical trial, a type of research study. Your study doctor(s), Mitchell Rosen, M.D. and Molly Quinn, M.D. from the University of California San Francisco Department of Obstetrics, Gynecology and Reproductive Sciences, Center for Reproductive Health will explain the clinical trial to you.

Clinical trials include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you are planning to undergo in vitro fertilization (IVF) for infertility**.**

Why is this study being done?

The purpose of this study is to understand whether processing of semen with an investigational microfluidic sperm sorting device (FERTILE) is superior to standard semen preparation methods for in vitro fertilization (IVF). In this study, subjects will have semen samples processed by a standard protocol or using a microfluidic processing device. The device contains channels through which only healthy, motile sperm are thought to be able to swim. Raw semen is placed in an inlet while sorted sperm is collected at an outlet. No chemicals or external forces are applied to the sperm. The microfluidic sperm sorting device is not available for clinical use outside of this study. It is not approved by the United States Food and Drug Administration and is considered investigational.

DxNow, the manufacturer of the investigational device being used in this study, is providing the study device at no cost to the researcher or research participant. Dr. Rosen is an unpaid member of the Scientific Advisory Board of the company that is donating the sperm sorting devices for this study.

How many people will take part in this study?

About 300 individuals will take part in this study

What will happen if I take part in this research study?

If you elect to participate in this research study, no additional visits or testing will be required. The only deviation from standard laboratory procedures will involve preparation of the unprocessed sperm sample by a microfluidic sperm sorting device rather than standard centrifugation and separation methods.

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in any group.

  - **If you are in group 1:** semen for IVF will be processed by standard clinic protocol involving centrifugation (spinning of the sperm) and other separation methods to isolate sperm.
  - **If you are in group 2:** semen for IVF will be processed by a microfluidic sperm sorter to isolate sperm.

- **Study location:** All study procedures will be done at 499 Illinois Street

How long will I be in the study?

You will be enrolled in the study at the start of the controlled ovarian stimulation cycle. The study procedure will take place when sperm is produced for IVF (at the time of the egg retrieval). If a pregnancy does not result from the IVF cycle under study, the study will conclude with a negative pregnancy test or upon discovery that there are no viable embryos for transfer. In the setting of a positive pregnancy test, the study will not conclude until data regarding the health of any offspring is provided as per Society for Assisted Reproductive Technology (SART) reporting requirements. If a miscarriage occurs, the study will conclude at the time of a documented miscarriage.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

- **Randomization risks:** You will be assigned to a treatment program by chance, and the treatment you receive may prove to be less effective than the other study treatment(s) or other available treatments.
- The microfluidic sperm sorting device may be associated with lower absolute yield of viable sperm for fertilization.
- Furthermore, while unlikely, it is possible that use of the sperm sorting device may harm the sperm. If this were to occur, damaged sperm would be unlikely to fertilize an egg. It is possible that damaged sperm could fertilize an egg, forming an embryo which could be transferred to the uterus. If a pregnancy results, it remains possible that harm to the fetus or offspring could occur.

- For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

If you are in the group that receives microfluidic sperm sorting and it proves to improve IVF outcome, you may benefit from participating in the study, but this cannot be guaranteed.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Undergoing IVF without being in a study.
- Taking part in another study.
- Getting no treatment.

Please talk to your doctor about your choices before deciding if you will take part in this study.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form will be added to your UCSF medical record. Therefore, people involved with your future care may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The University of California
- The Food and Drug Administration (FDA), involved in keeping research safe for people.

What are the costs of taking part in this study?

The costs of all visits, treatments, and tests related to your IVF cycle will be billed to you or your insurance carrier. There will be no extra charges related to participation in this study. Financial counselors are available to discuss this with you.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor(s) Mitchell Rosen, MD or Molly Quinn, MD at (415) 353-7475.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date _____ Participant's Signature for Consent _____

Date	Person Obtaining Consent