Northwell Health
Campus: North Shore University Hospital
Consent for Participation in a Research Study

Protocol Title: Safety and Efficacy of Sonohysterosalpingography for the Evaluation of Infertility
Sponsor: Katz Institute for Women's Health (KIWH)

Principal Investigator: John Pellerito, MD
Institution: Northwell Health
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Introduction

You are being asked to join a research study. The purpose of a research study is to answer specific questions, sometimes about the safety of a drug or device and how well it works. Being in a research study is different from being a patient. When you are a patient, you and your doctor have freedom in making decisions about your healthcare. When you are in a research study, the researcher will follow the rules of the research study as closely as possible, while monitoring your health.

This consent form will explain the purpose of the study, what you will be asked to do, and the potential risks and benefits. It will also explain that you do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study. If you decide to participate in this study, you will be asked to sign and date this consent form to indicate that you agree to participate. This process is called informed consent.

This consent form is written from the point of view of a research participant. If you are a legally authorized representative or a next of kin that will be providing consent, the words "you" and "your" should be read as "the research participant." As the participant's legally authorized representative or next of kin, you are being asked to give consent for the participant to be in a research study. You are being asked to do this because the participant is not able to give consent. When making this decision, you should take into account the wishes of the participant. If you agree to allow the participant to take part in this research, the participant will also be asked to give consent if the ability to make healthcare decisions is regained.

Please read this form carefully. It tells you important information about the research study. A member of our research team will also talk to you about taking part in this research study. If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you.

Why is this research study being done?
You are being asked to participate in this study because you are at least 18 years old and are undergoing the work-up of infertility. As part of your infertility work-up, your doctor has determined that you will need to get a Hysterosalpingogram (HSG) for the evaluation of fallopian tube patency. Participation in this research study will have no effect on the timelines of your diagnostic work-up and/or your medical treatment by your physician.

The HSG is a transvaginal procedure that uses radiation and iodinated contrast to visualize the fallopian tubes. The HSG is the "gold standard" for determining fallopian tube patency. It is often accompanied by the Sonohysterogram, a transvaginal procedure that uses ultrasound and saline to visualize the uterus.

Another procedure that is also performed for the evaluation of fallopian tube patency is the Sonohysterosalpingogram (sonoHSG). This procedure uses agitated saline to produce air bubbles at the time of the Sonohysterogram which optimizes fallopian tube visualization. The sonoHSG is free of radiation and use of contrast. In this study, in order to produce the air bubbles at the time of the sonohysterogram, we will be using a continuous saline-air device that may produce a technically superior image. The use of this device to produce air bubbles during the sonohysterogram equals to the sonoHSG.

In this study, both the HSG and sonoHSG will be done consecutively on the same day and same visit. The HSG will be done as your standard of care diagnostic procedure and the sonoHSG will be done as part of research. You will not be charged for the cost of the sonoHSG. Having both procedures performed consecutively will reduce the burden of having to return for an additional visit in addition to reducing any pain and discomfort you may feel.

As a result of this study, the Radiology Department and Northwell Health Fertility will work together to encourage, educate, and support physicians to promote the utility of sonoHSG as the first imaging examination for the infertility workup.

How many people will take part in this study?
This research study hopes to enroll 30 participants.

How long will I take part in this research study?
It will take you up to 3 weeks to complete this research study. Your first visit will include having both the HSG and sonoHSG performed and your second visit will be a follow-up over the phone between 1 to 3 weeks after the initial procedure visit. After this phone follow-up, your participation in the study will come to an end.

What will happen in this research study?
If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures. Whenever possible, we will do the following visits when you would normally be coming to the hospital for your regular care. If any of the measurements or tests listed below are done as part of your regular care, we will use those for the study. We will not repeat any tests for the study if they are already being performed as part of your regular care.

As part of standard of care, you will have the HSGperformed. As part of this research study, you will have the sonoHSG performed consecutively on the same day and visit as the HSG. The order of the procedures will be randomized and this randomization scheme will be performed after you have given consent to participate in this study. The study investigators will be informed of the randomization order but will be blinded to the results of each procedure in order to eliminate potential bias.

As part of this study, you will complete an evaluation consisting of a Pain Scale rating for all procedures performed. All pain scale surveys will be administered verbally immediately after each procedure.

After you have completed both the HSG and sonoHSG along with the Pain Scale surveys, you will be followed-up via phone between 1 to 3 weeks after the date of your first visit. The purpose of this phone follow-up is to collect information about any complications or infections that may have occurred. After this phone follow-up, your participation in the study will come to an end and we will not collect information about you for the purpose of this study after this point.

Following are the study events listed out in the order that they will occur with brief explanations of what will happen as part of each event. In addition, each procedure has been classified as either standard of care (SOC) or research (R) in order to distinguish the procedures taking place only for the purpose of this study.

Prescreening/Baseline Visit:
At this visit, we will:

- Collect some demographic information about you
- Ask about your medical history
- Collect information about what medications you are taking

Visit 1:

- Pregnancy test
- Date of last period
- Information about intercourse between last period and now
- Explanation of HSG and SonoHSG

Placement of Catheter: (**SOC**)

- Verbally administer survey with pain scale for catheter placement (**R**)

HSG:

- We will collect fallopian tube patency (**SOC**)
- Verbally administer survey with pain scale for HSG (**R**)

Sonohysterosalpingogram (sonoHSG):

- We will collect fallopian tube patency (**R**)
- Verbally administer survey with pain scale for sonoHSG (**R**)

Follow-Up via Phone: (R)

- Collect information about infections that may have occurred
- Collect information about other complications that may have occurred

What are the risks of the research study? What could go wrong?
As part of this research study you are having a sonoHSG performed which utilizes ultrasound modality. Ultrasound exams involve minimal risk because they are free of radiation. Some of these risks, although rare, may include the following:

- Discomfort
- Skin irritation
- Bruising

Risks of the sonoHSG, although rare, may include the following:

- Infection of the uterus/pelvis
- Bleeding

Interviews/Questionnaires
Some of the questions we will ask you are personal. You may feel embarrassed or stressed. You may ask to see the questions before deciding whether or not to take part in this study.

Incidental Findings
There is a possibility that while reviewing your sonoHSG ultrasound images we may see an abnormality that may have health implications that we did not expect to see. This is what is called an "incidental finding." If we see an incidental finding, the appropriate referral will be made.

This study is neither designed nor intended to detect health problems. The imaging that you will have as part of research will not substitute for an appropriate medical examination by a qualified health care provider. Your research images will be reviewed by a doctor specialized in interpreting such images.

What are the benefits of this research study?
This research study will reduce the number of visits you make by performing the HSG and sonoHSG consecutively in one visit. This reduces the burden of having to return separately for both procedures in addition to reducing the pain potentially experienced by placement of the catheter. Only one catheterization will be done for both the HSG and sonoHSG as opposed to two catheterizations if you were returning to have each procedure performed separately. All research procedures will be performed at no cost to you.

The information we learn about these procedures may also help patients undergoing the work-up of infertility in the future.

If you do not want to take part in this research study, what are your other choices?
If you do not want to be part of this research study, you do not have to participate.

Are there any costs for being in this research study?
This research study is funded by Katz Institute for Women's Health. You will not have any added costs from being in this study. All study related visits, procedures and medications will be given to you at no cost. Neither you nor your insurance company will be billed for your participation in this research. Your insurance will only be billed for the HSG because that is your standard of care procedure. The sonoHSG will be performed at no cost to you.

Will you receive any payments for participating in this research study?
You will not receive any payment for your participation in this research study.

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?
It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:
- failure to follow instructions,
- failure to show up for study visits,
- it is not in your best interest to continue on this study, or the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data (or samples) already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?
If you agree to be in this study, we will collect health information that identifies you. We may collect the results of tests, questionnaires and interviews. We may also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from Federal and state government oversight agencies, such as the Department of Health and Human Services
- Representatives from Northwell Health's Human Research Protection Program (a group of people that oversee research at this institution)

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Dr. John Pellerito
North Shore University Hospital
300 Community Drive
Manhasset, NY 11030

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Will information about this study be available to the public?
A description of this clinical trial will be available on http://www.Clinical Trials.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 website at any time.

Does the investigator of this study receive money if you take part?
The investigators on this study receive money to conduct the study, but do not financially benefit from your participation. The money they receive is to pay them back for the costs of conducting the research study. Funding for this research study is provided by Katz Institute of Women's Health. If your doctor is an investigator for this study s/he is interested in both your healthcare and the conduct of this research. You do not have to take part in a research study conducted by your doctor.

Who can answer your questions about this study?
If you have any questions about the study, you may call Dr. John Pellerito at 516-562-4800. If you have questions about side effects or injury caused by research you should call Dr. John Pellerito at 516-562-4800. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 465-1910.

A signed copy of this consent form will be given to you.

[Signature Page Follows]

Summation/Signature
You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____ _____ _____
Witness's Printed Name Witness's Signature Date
(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

Investigator's Statement
In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____
Investigator's signature **Date**

_____
Investigator's printed name