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IRB APPROVED
Jan 16, 2019

SUBJECT CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE: Vaginal tactile imaging in assessment of pelvic floor conditions before the delivery

PROTOCOL NO.: VTI10
WIRB® Protocol #20183400
Pro2018002747

SPONSOR: Advanced Tactile Imaging, Inc. (ATI), Trenton, NJ and Eunice Kennedy Shriver National Institute of Child Health &Human Development (NICHD)

INVESTIGATOR: Todd Joshua Rosen, MD
Clinical Academic Building
125 Paterson Street Suite 2140
New Brunswick, New Jersey 08901
United States

STUDY-RELATED PHONE NUMBER(S): Dr. Todd Rosen
732-235-6632
732-491-5787 (24 hours)

Shama Khan
732-357-5554

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the Study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Who is conducting this research study?

Dr. Todd Rosen is the Principal Clinical Investigator of this clinical study. A Clinical Principal Investigator has the overall responsibility for the conduct of the study. However, there are often other individuals who are part of the research team.

Dr. Todd Rosen may be reached at:
Rutgers Robert Wood Johnson Medical School
125 Paterson Street Suite 2140
New Brunswick, NJ 08901
732-235-6632

The study doctor Dr. Todd Rosen or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Who is the sponsor of this study?

Advanced Tactile Imaging, Inc. / Eunice Kennedy Shriver National Institute of Child Health &Human Development (NICHD) / NIH

Why is this study being done?

The mechanical demands placed on the pelvic floor structures during vaginal delivery often exceed physiological tissue limits, resulting in maternal childbirth trauma. Injury to the perineum, vaginal supportive tissues, pelvic floor, and sphincter muscles cause pelvic pain, infection, and dyspareunia (painful intercourse) in the short term, as well as pelvic organ prolapse, stress urinary incontinence and anal incontinence in the long term. Pregnancy and vaginal delivery are considered to be the main risk factors in weakening the pelvic floor support. This is considered to be due to damage to the endopelvic fascia (tissues which serve to suspend the female pelvic organs inside the pelvis), pelvic floor muscles, and peripheral nerves.

Several studies support that the incidence of pelvic floor disorders (PFD) depends on the mode of delivery. Numerous antepartum techniques and intrapartum obstetric interventions have been described and introduced to reduce the risk of maternal trauma during the second stage of labor; however, no justifications were presented why one or another intervention is optimal for the patient. Despite the obvious fact that vaginal delivery is a biomechanical process, currently there are no tools to objectively measure the biomechanical properties of pelvic tissue in women before the delivery. Such data is essential to scientifically guide clinical decisions regarding the delivery mode and/or intrapartum interventions to reduce childbirth trauma. Thus, the key unanswered question is: Can an individual parturient's risk for pelvic floor trauma per every possible intervention and delivery mode be predicted using objective data pertaining to the biomechanical properties of soft tissue components affected during delivery?

In the last decades, Elasticity Imaging or elastography, has emerged. Elastography allows visualization and quantitative assessment of the mechanical properties of soft human tissues. The Vaginal Tactile Imager (VTI) allows acquisition of 3D elasticity data for pelvic soft tissues which are influenced during the delivery. Its use in this study is experimental.

The long-term goal of this project is to develop, validate, and integrate into clinical practice a new paradigm and a novel device to simultaneously measure the biomechanical properties of various pelvic structural components that are impacted during vaginal delivery, and to develop a risk prediction model of maternal birth injury. Ultimately, such approach will enable individualized patient counseling regarding the mode of delivery and/or the need for obstetrical interventions to reduce childbirth trauma.

Why have you been asked to take part in this study?

You have been asked to participate in this study to allow taking a 3D elasticity image of your pelvic floor structures which may be influenced during the vaginal delivery.

Who may take part in this study? And who may not?

Any patients may participate if they are women 21+ years of age with prior vaginal delivery (parous) and having completed the 35th week of pregnancy with fetus in vertex position and premise of vaginal delivery.

You may not participate in this study if you have any of the following:

1. Prior perineal surgery
2. HIV or hepatitis B positive serology
3. Warty lesions on the vulva
4. Extensive varicose veins on the vulva
5. Active skin infection or ulceration within the vagina/vulva (Herpes infection)
6. Severe hemorrhoids
7. Stillbirth or extensive congenital abnormalities of the fetus

Because this study involves a vaginal examination, any patient that cannot tolerate a vaginal examination or the position needed to perform a vaginal examination will be excluded.

How long will the study take and how many subjects will participate?

The study will be performed in a single session lasting 3-5 minutes for each participant. There will be several available dates to choose from for scheduling. Ten pregnant participants will be included in the study.

What will you be asked to do if you take part in this research study?

During the procedure a vaginal probe will be inserted and manipulated in various directions to obtain the required images. We do not anticipate the VTI scan procedure will cause any pain, but you will be asked to fill out anonymously the Pain and Comfort Level Form.

What are the risks and/or discomforts you might experience if you take part in this study?

Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include: risks normally associated with standard manual palpation and transvaginal ultrasound, such as extremely rare possibility of physical damage of the vaginal, cervix tissue and infection. Other risks include software/hardware malfunction, toxicity, allergic reaction, electrical shock, and breach of confidentiality

The study involves potential discomfort from a pelvic examination and pressure onto the soft tissues as during physical examination. You may request to discontinue the scan with VTI at any time, if you feel a discomfort or a pain.

Are there any benefits for you if you choose to take part in this research study?

The benefits of taking part in this study may be: improved outcome of the most remarkable and painful event in woman's life, given the large proportion of women who suffer from pelvic floor disorders caused by childbirth. However, you will receive no direct benefit from taking part in this study.

What are your alternatives if you don't want to take part in this study?

This is not a treatment study. Your alternative is not to take part in this study.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?

There are no costs to you associated with taking part in this study.

Will you be paid to take part in this study?

You will receive $50.00 payment after you complete the study to help cover your expenses and inconvenience.

How will information about you be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

Information obtained from this research will be kept confidential so that neither the investigator nor the sponsor will link your individual research results with your identity. Your examination and imaging results will be given a code number. Any results and other relevant clinical information will be linked with the sample's code number. Your name, date of birth, address, or other personal identifying information, will not be linked with your testing results.

The research is not intended to give you clinical information. Information resulting from the research will not be entered into your medical records.

Neither you, nor your family members, nor outside parties or investigators will be allowed to look at your individual research results.

It is possible, however, that members of regulatory authorities, such as the U.S. Food and Drug Administration (FDA), the Rutgers University Institutional Review Board, Western Institutional Review Board® (WIRB®) or other persons required by law may be allowed to look at this information.

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.

What will happen if you are injured during this study?

It is possible that during the course of this study, new adverse effects of the Vaginal Tactile Imager that result in personal injury may be discovered. The University will make appropriate referrals for medical treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of

this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of your data, but you understand that you must do this in writing to Dr. Todd Rosen Division of Maternal Fetal Medicine 125 Paterson Street Suite 2140 New Brunswick, NJ 08901.

Any data that has already been sent to Advanced Tactile Imaging or to the Data Coordinating Center cannot be withdrawn because there may not be any identifiers to link the data with you.

Who can you call if you have any questions?

If you have any questions about taking part in this study, concerns or complaints about the research, or if you feel you may have suffered a research related injury, you can call the study doctor:

Dr. Todd Rosen
Rutgers-Robert Wood Johnson Medical School
Division of Maternal Fetal Medicine
732-235-6632 or 732-491-5787 (24 hours)

Or

Shama Khan, MPH M.S., LGC
Study Coordinator
732-357-5554

If you have any questions about your rights as a research subject, or concerns or complaints about the research, you can contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

OR

IRB Director
(732)-235-9806 New Brunswick/Piscataway

Human Subject Protection Program
732-235-8578 - New Brunswick

What are your rights if you decide to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Information about you and your health is personal and private, so this information generally cannot be used in this research study without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of this research study and how will my health information be utilized in the study?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the question that are being asked in the research.

What information about me will be used?
By taking part in this study, you should understand that the study collects demographic data and data on your health without disclosing your identity. This data will be reported to Advanced Tactile Imaging (Trenton, NJ) in de-identified form for data processing.

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University researchers involved in the study;
- Non-Rutgers researcher on the study team: Advanced Tactile Imaging, Inc., 1457 Lower Ferry Road, Trenton, NJ 08618
- The Institutional Review Board and Rutgers Compliance Boards;
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services;
- The Food and Drug Administration (FDA);

- The VTI device developer, Advanced Tactile Imaging, Trenton, NJ, and their designees.
- The primary study sponsor Eunice Kennedy Shriver National Institute of Child Health &Human Development (National Institutes of Health).
- Western Institutional Review Board® (WIRB®).

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study).

If I say yes now, can I change my mind and take away my permission later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes but change your mind later for the use of your information in the research, you must write to the researcher and tell him or her of your decision:

Dr. Todd Rosen may be reached at:
Rutgers Robert Wood Johnson Medical School
125 Patterson Street, Suite 2140
New Brunswick, NJ, 08901
732-235-6632
Or
732-491-5787

How long will my permission last?

The data will be kept as long as the study product is marketed, or for 10 years.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered. I agree to take part in this research study.

Subject Name: _____

Subject Signature: _____ Date: _____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject have been accurately answered.

Investigator/Person Obtaining Consent (printed name): _____

Signature: _____ Date: _____