

KAISER FOUNDATION HOSPITALS PATIENT'S NAME: _____

SOUTHERN CALIFORNIA PERMANENTE M.R. #: _____
MEDICAL GROUP

STUDY #: _____

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY OF

Ancor for Robotic Sacrocolpopexy: **ARiSe**

SPONSOR: Kaiser Permanente

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Downey, CA 90242

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You are invited to be in a research study. Taking part in this study is voluntary.

This informed consent form tells you about the purpose, risks, and benefits of this research study. You may ask questions and take time to think about the study before you decide to join it. You should decide if you want to participate in the study only when you have received all the information you need.

Your doctor or health care provider may be working on this research study. He or she is interested in your healthcare as well as the conduct of this study. If that makes you feel the doctor can't be objective about the best care for you, you may ask for another doctor or staff member who is not involved in this research.

WHAT IS THIS STUDY ABOUT?

You are being invited to participate in a study called “**Anchor for Robotic Sacrocolpopexy – ARiSe**” because you have decided to have surgery to correct prolapse of your vagina and eliminate the bulge associated with it. Robotic Sacrocolpopexy is a surgery designed to correct the prolapse or bulging of your vagina and is performed through small incisions on your abdomen. The procedure involves attaching a piece of mesh to your vagina and connecting that to a strong supporting ligament in your pelvis. The mesh is a synthetic polypropylene, similar to material used to correct hernias in other areas of the body. It will be attached to your vagina with sutures (stitches) or anchors.

A physician can choose from different methods of attachment to attach the mesh to the vagina, but we don't have enough information about which method provides the best symptom relief while causing the fewest problems (complications) after surgery.

Two common methods used to attach mesh are sutures and anchors. We currently use both suture and anchor in our practice but it is unclear which of the both has the best results when used to attach the mesh for prolapse (bulging in the vagina) repair. If you agree to participate in the study, you will be randomly assigned (like flipping a coin) to one of these two methods of attachment (suture or anchor).

We do not know if one treatment will work better than the other. The way to find out if one treatment is better than the other is to compare them.

DO I HAVE TO JOIN THIS STUDY?

You do not have to be in this study. Participation in this study is entirely voluntary. You may choose not to be in this study. You will still receive care from your doctor. You may leave this study at any time without affecting your future medical care.

HOW LONG IS THIS STUDY?

Participation in this study will last 6 months from the date of surgery.

If you choose to take part in all the study visits, you will be in this study for about 6 months from the time of your prolapse surgery.

If you join the study, you can decide to stop at any time for any reason. If you decided to stop, you would need to talk with the Principal Investigator so you leave the study in a safe way.

The research study doctor could also decide to take you out of this study. This might happen if we find out that it is not safe for you to stay in the study. Or it might happen if you cannot come to enough of the study visits. If we ask you to leave the study, we would always explain why.

If you are a Kaiser Health Plan member, and lose Kaiser Foundation Health Plan coverage, you may be withdrawn from this study.

WILL I BE COMPENSATED IF I JOIN THIS STUDY?

You will not be paid for participation in this study.

IF I AGREE TO JOIN THIS STUDY, WHAT WOULD I NEED TO DO?

Your participation in the study will include the events explained in detail below.

Before Surgery (Baseline: 40-60 Minutes)

The study nurse will review your medical record and ask you about yourself and your medical history. Your height and weight will be recorded. A pelvic examination will be done to measure the prolapse, (bulging in the vagina). During the pelvic exam, you will be asked to bear down and measurements will be taken. You will be asked to squeeze your pelvic muscles to test the strength of your pelvic muscles. These tests are normally done when you see a doctor for prolapse (bulging in the vagina). Because most of the information listed above has already been collected in your medical record as part of your clinical care, the information may be copied onto the research forms instead of repeating the examination.

If you are capable of child-bearing (getting pregnant), a sample of urine will be collected before the study begins in order to be as sure as possible that you are not pregnant.

You will also be asked to complete some questionnaires which may take 10 minutes to complete

The collection of this information should take 40-60 minutes.

Randomization at Surgery

If you agree to participate in the study, you will be randomly assigned (like flipping a coin) to one of these two attachment techniques:

- An anchor (absorbable fastener) or;
- A suture (stitch) with knots

You have an equal chance (50%) of being assigned to one of the two attachment techniques.

The attachment assignment (randomization) will occur in the operating room on the day of your surgery. Neither you nor your doctor will choose whether you will have the

anchor (absorbable fastener) or suture (stitch) with knots for surgery. You will not know which attachment technique you had, but you can find out at the end of the study (6 months after your surgery), or earlier if needed for medical reasons.

After Surgery (Follow-Up Visits: 40 Minutes)

All study participants will have 2 in-person standard of care visits over the 6 months after surgery. Both of these visits will be timed to coordinate with your routine visits to see your surgeon.

The timing of these visits after surgery is:

- 4-6 weeks
- 0-6 months

At each visit, the study nurse will ask how you are doing in general, about any gynecological or urinary problems, and about any medical care you have received since the previous visit. At these visits you will also be examined by a clinician to ensure that your vaginal tissue is healing and to assess pelvic muscle strength and prolapse (bulging in the vagina) repair. In addition you will be asked to complete questionnaires which may take 10 minutes to complete.

If you choose to be in this study, you will need to come to 2 visits (4-6 week visit and 6 month visit) over a period of 6 months.

We appreciate your commitment to take part in this study. We realize that individual circumstances may change over the months and at times an in-person research visit may not always be possible. Therefore, to obtain as much valuable study information as possible, if you are not able to come in for an in-person visit, information may be collected during an office visit, a telephone call by the study nurse or an interviewer from Kaiser Permanente.

WHAT ARE THE POSSIBLE HARMS OR RISKS IF I JOIN THIS STUDY?

Risk and Precautions

Your surgeon will talk to you about the risks involved with your prolapse (bulging in the vagina) surgery. This surgery is done as part of your clinical care and is not considered research. Your surgeon is experienced in doing the surgeries.

Prolapse Assessment

A pelvic examination is required for this assessment. You may feel some discomfort; however, the examiner is trained to minimize discomfort during the exam.

Questionnaires

You may feel uncomfortable answering some questions on the questionnaires. Some questions are about sensitive and personal topics and may make you uncomfortable. You could skip any questions you do not want to answer.

Medical Record Review

If you decide to take part in this study, we will need to collect some information from your medical records.

There may be other risks that we do not know about.

WHAT ARE THE POSSIBLE BENEFITS IF I JOIN THIS STUDY?

There is no guarantee that you will benefit from participating in this study.

WHAT OTHER OPTIONS DO I HAVE?

You do not have to participate in this study to get health care at this medical center. Your condition can be treated without your participation in this study. You can choose to have your scheduled surgery without being in this study. Ask your doctor to talk about the options with you.

HOW WOULD YOU KEEP MY INFORMATION CONFIDENTIAL?

Your study records, and the records of the medical treatment that you receive, will be protected according to the current standards. Your study records and the records of the medical treatment that you receive may be reviewed by federal and state agencies, such as the Committee for the Protection of Human Subjects. You will not be personally identified in any reports or publications that may result from this study.

Additional information about the use and disclosure of your protected health information is contained in the Authorization to Use and Disclose Protected Health Information included at the end of this consent form. Your signature on the Authorization will be required for you to participate in this research study

WOULD IT COST ME MONEY TO BE IN THE STUDY?

The surgery and physician visits at baseline, 4 - 6 weeks and 6 month are part of standard clinical care and will be provided pursuant to your health care service agreement with Kaiser Foundation Health Plan that may include co-payments or other applicable charges. If your prolapse (bulging in the vagina), bladder or bowel symptoms get worse following surgery, or if other complications after surgery occur, all costs associated with the treatment of these complications are considered part of your standard clinical care.

Other medication that you use or may require during study period will not be covered by the study. Any health expenses not related to the study will not be covered by the study.

COMPENSATION FOR STUDY-RELATED INJURY

If you are injured or become sick as a direct result of the study procedures, medical treatment will be offered to you pursuant to the terms of your plan benefits. These benefits are described in your Evidence of Coverage or Summary Plan Description. You may have to pay co-payments, coinsurance and/or deductibles. Other than reimbursement of medical treatment expenses, the Sponsor has no plans to provide any other form of compensation for study-related injury or illness. By agreeing to participate in this study, you do not give up any legal rights to other remedies that may be available to you in connection with an injury or illness caused by the study drug or study procedures.

WHERE I CAN LEARN MORE ABOUT THIS STUDY?

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 DOES MY SIGNATURE ON THIS FORM MEAN?

My signature on this form would mean that I acknowledge:

1. Personal information about me that is collected in this study will be protected to the full extent of the law. No information from this study that could be linked to me will be released without my consent.
2. The results of this study may be reported in articles, books or at meetings. My identity will not be revealed at any time. Research records will be kept confidential to the extent provided by law. All study records will be kept in a locked room and accessed only by staff working on this research study.
3. I will be notified if there is important new information discovered during the course of the study.
4. Being in this study is my choice. I may decide to leave this study at any time. If I choose not to be in the study or leave the study, it will not affect my insurance benefits or my future medical care at Kaiser Permanente.
5. I may be asked to leave the study at any time for medical reasons, if the researcher feels that it is in my best interest, or if the study is stopped.
6. My questions regarding this study have been answered. If I have any questions about this study or if I experience a study-related injury, I may contact:

San Diego:

Shawn A. Menefee, MD 619-221-6274

Downey/ Bellflower:

John N. Nguyen, MD 562-657-2642

If I have any questions about my rights as a research subject, I may contact

Armida Ayala, PhD, Director, Human Research Subjects Protection Office at
626-405-3665 or armida.ayala@kp.org

1. If I am injured or become sick as a direct result of taking the study drug or procedures, medical treatment will be offered to me pursuant to the terms of my plan benefits. These benefits are described in your Evidence of Coverage or Summary Plan Description. You may have to pay co-payments, coinsurance and/or deductibles. The Sponsor will reimburse the reasonable costs of any medical treatment of a study-related injury or illness provided that you have followed the instructions of the study

doctors. Other than reimbursement of medical treatment expenses, the Sponsor has no plans to provide any other form of compensation for study-related injury or illness. By agreeing to participate in this study, you do not give up any legal rights to other remedies that may be available to you in connection with an injury or illness caused by the study drug or study procedures. I may be withdrawn from the study if I lose my Kaiser Foundation Health Plan coverage.

I have read the entire consent, including the Supplemental HIPAA Authorization and Experimental Subject's Bill of Rights and voluntarily consent to participate in this research study conducted by the physicians or employees of Southern California Permanente Medical Group and/or Kaiser Foundation Hospitals.

Your signature shows that the research study has been explained to you and all of your questions have been answered. ***If you still have questions or do not understand what this study is about, do not sign this form.*** Give this form back to the study staff and get more information.

A copy of this signed and dated Informed Consent Form will be given to me for my records

Printed First and Last Name of Participant/ Legally
Authorized Representative

Relationship to Participant

Signature of Participant/Legally Authorized
Representative

Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

Additional witness signature for studies consenting with the Short Form:

Printed First and Last Name of Witness (the
translator may act as a witness only if they
are not the person obtaining consent)

Signature of Witness

Date

AUTHORIZATION TO USE YOUR PROTECTED HEALTH INFORMATION

What is protected health information?

Protected health information is any of your health information that can be traced back to you. We need your authorization (permission) to use your protected health information in this research study. We may use any of the protected health information that is available in your Kaiser Permanente Medical Care Program records. The protected health information that we will use and share for this study includes all of the following:

- Your past, present and future health information;
- Demographic Information that can be used to contact you such as: date of birth, address, phone number, medical record number;
- The results of your examinations, imaging studies, medical tests and laboratory work;
- Reimbursement and insurance information

Who else will see my information?

This information may be shared with the following

- The Kaiser Permanente Southern California Institutional Review Board (IRB)
- Individuals and departments that participate in, or provide support to, the research including, but not limited to, research study investigators, research coordinators, research nurses and contracts & grants departments

Once we have shared your information we cannot be sure that it will stay private. If **you** share your information with people outside the research team, it will no longer be private. Your name will not be used in any report that is written.

How long will Kaiser Permanente researchers and others use and share my information?

Kaiser Permanente researchers will use and share your information until the research is completed.

What if I change my mind about sharing my research information?

If you decide not to share your information anymore:

- The research team can continue to use any of the protected information that they already have.
- You will no longer be a part of the research study.
- You will still get the same medical care that you've always had at Kaiser Permanente.
- You must write to the study principal investigator and tell him that you no longer want to share your information. Write to the study principal investigator at:

Shawn A. Menefee, MD
3250 Fordham Street, Bldg. A
Ob/Gyn Department
San Diego, CA 92110

Do I have the right to see and copy my research information?

You cannot see your research information while the study is going on, unless the information is also being used for your health care. There may be other limitations on access to medical information unrelated to this study. Once the study is over, you can ask the Principal Investigator to see any research information that is maintained by Kaiser Permanente.

If you agree to share your information you should sign this form below. You will be given a copy of this form.

I agree to share my information as described in this form

Printed First and Last Name of
Participant/ Legally Authorized Representative

Relationship to
Participant

Signature of Participant/Legally Authorized
Representative

Date

If you have questions or concerns about your privacy and the use of your protected health information, contact the investigator at the telephone number listed in the consent form.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of a signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Original – Chart or Study

Copy – Patient