Evaluating the Effect of Preoperative Patient Education on Postoperative Opioid Consumption, Storage, and Disposal after Urogynecologic Procedures

Protocol ID: 2017-11833

Informed Consent Form
06/04/2018

UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Evaluating the Effect of Preoperative Patient Education on Postoperative Opioid Consumption, Storage, and Disposal after Urogynecologic Procedures

You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed below will be available to answer your questions.

RESEARCH TEAM
Kristen Buono, MD
Fellow, Female Pelvic Medicine and Reconstructive Surgery (FPMRS)
Obstetrics & Gynecology
(714) 456-6807
24-hour pager (714) 506-6351

Other Researchers

Felicia Lane, MD
Professor
Obstetrics & Gynecology

Taylor Brueseke, MD
Assistant Professor
Obstetrics & Gynecology

Bhumy Davé, MD
Assistant Professor
Obstetrics & Gynecology

Sonia Dutta, MD
Fellow, FPMRS
Obstetrics & Gynecology

Neha Sudol, MD
Fellow, FPMRS
Obstetrics & Gynecology

STUDY LOCATIONS:
UC Irvine Medical Center
Kaiser Permanente Orange County – Irvine Medical Center

WHY IS THIS RESEARCH STUDY BEING DONE?
The purpose of this research study is to evaluate the effect of specialized patient education prior to surgery on the amount of opioid medications that are consumed after the surgery. Additionally, we will evaluate the effect of the specialized patient education on patients' storage and disposal patterns of opioid medications after the surgery.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 73 participants will take part in the research at UCI. A total of 146 participants will be asked to participate across all study sites.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?
Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements
You can participate in this study if you are at least 18 years of age or order and are undergoing a surgical procedure for the indication of pelvic organ prolapse.

Exclusion Requirements
You cannot participate in this study if you are not able to understand the educational pamphlets or complete the patient questionnaires that are written in English. Additionally, if you are undergoing a joint surgery with another surgical service (such as colorectal surgery), you will be excluded from the study.

HOW LONG WILL THE STUDY GO ON?
This study includes approximately 3-5 clinic visits over a period of 3-6 months. Patients will undergo the educational intervention either during a clinic visit prior to the surgery or on the day of the surgery. Patients in both the interventional and control arms of the study will be assessed during clinic visits 2 weeks and 6 weeks after the surgery. Additionally, the researchers would like to evaluate your medical record 12 weeks and 12 months after your surgery to evaluate for any additional opioid prescriptions.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?
Before you can participate in the main part of the study...
You will need to have "screening" exams, tests or procedures. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include evaluation of your ability to understand and complete written questionnaires and evaluation of your planned surgery. If your surgery is not included in the list of surgeries that will be evaluated during this particular study, you will not be invited to participate.

During the main part of the study...
If the screening exams, tests and/or procedures show that you can continue to be in the study, and you choose to take part, then you will have the following procedures and tests done. The main study tests and procedures include:

1. At either the clinic visit before your surgery (preoperative clinic visit as noted in the table below) or on the day or your surgery, you will be provided with an educational pamphlet about opioid medications. One of the research investigators will verbally review the pamphlet with you and you will have the opportunity to ask questions. Additionally, you will complete two patient questionnaires at this time. The first questionnaire will evaluate your generalized pain score and the second questionnaire will evaluate your opinions and knowledge about the risks of opioid medications and safe storage and disposal practices. Both questionnaires will take approximately 5-10 minutes to complete. These are the standard questionnaires that you will complete several times throughout the study period.

2. You will receive the prescriptions for the medications you will be taking at home after your surgery. It is recommended that you obtain these medications prior to your surgery.

3. The decisions regarding your length of hospitalization and any medications to be administered either during your surgery or your hospital stay will be determined by your surgeon and are not influenced by your participation in the study.

4. One to two days prior to your first clinic visit after your surgery (2 weeks after surgery), you will be called on the telephone and reminded to bring your opioid medication bottle and remaining opioid tablets to the clinic appointment. At your first clinic visit two weeks after your surgery, the remaining number of opioid tablets will be counted. Additionally, you will complete two questionnaires and receive a second educational pamphlet about appropriate disposal methods for your unused opioid tablets.

5. During your 6 week postoperative clinic visit, you will complete the two postoperative patient questionnaires.

6. If you are unable to attend any of your scheduled clinic appointments after your surgery, you will be called on the telephone. You will be asked to count the number of remaining opioid tablets you have at home and the two patient questionnaires will be verbally administered over the phone.

8. The CURES (Controlled Substance Utilization Review and Evaluation System) 2.0 database and the University of California Irvine Medical Center electronic medical records will be reviewed for opioid medication prescriptions several times throughout the study. These databases will be reviewed once prior your surgery, at each clinic visit after your surgery, and again two times (12 weeks and 12 months) after your surgery is completed.

	Initial Clinic Visit	Preoperative Clinic Visit	Day of Surgery	2 week clinic visit after surgery	6 week clinic visit after surgery	12 weeks after surgery	12 months after surgery
Identify eligible patients	X	X					
Study consent obtained	X	X	X				
Patient Education Performed		X	X	X			
Patient Questionnaires Completed		X	X	X	X		
Evaluation of Medical Record	X	X	X	X	X	X	X

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?
You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. You should talk to the research team about any side effects you experience while taking part in the study.

Risks Associated with the Study Intervention
You will be assigned to a study group by chance (like a coin flip) rather than by a medical decision made by the researchers. As this is an educational intervention, there is minimal risk involved. Risks of the educational intervention include anxiety, psychological harm, or breach of confidentiality if study documents are compromised. Some of the procedures may cause embarrassment or anxiety, or the questions the researchers ask you may be upsetting or make you uncomfortable. If you do not wish to answer a question, you can skip it and go to the next question. If you do not wish to participate you can stop.

ARE THERE BENEFITS TO PARTICIPATING IN THIS STUDY?
Participant Benefits
Taking part in this study may or may not make your health better. While researchers hope that patient education prior to surgery will be more effective at reducing opioid consumption after surgery than the standard (usual) treatment, there is no proof of this yet.

If you are in the group that receives patient education prior to surgery and it proves to reduce your use of opioid medications after surgery, you may benefit from participating in the study, but this cannot be guaranteed.

Benefits to Others or Society
This study will help researchers learn more about the effect of patient education on opioid consumption after surgery. It is hoped that this information will help reduce the amount of opioid medications consumed by patients after surgery, which would reduce the risks of side effects and opioid dependence in the future.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?
If you decide not to participate, or if you withdraw from this study before it is completed, your other choices may include:
- Getting standard treatment for your condition without being in a study.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?
Compensation
You will not be compensated for your participation in this research study.

Reimbursement
You will not be reimbursed for any out of pocket expenses, such as parking or transportation fees.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?
There is no cost to you or your insurer for your participation in this study. The evaluations prior to and after your surgery will be performed during routine clinic exams that would occur even if you were not participating in the study. You will be responsible for any deductibles or co-payments that would normally be associated with these standard medical costs. There may be out-of-pocket expenses such as parking and transportation fees.

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?
You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to complete an exit telephone interview.

If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI should be made in writing.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?
Subject Identifiable Data
All identifiable information collected about you will be kept in a separate key that will only be accessed by the research investigators. Clinical information from your surveys and medical records will be uploaded

into a de-identified password protected database system that will only be accessed by the lead researcher.

Data Storage
Research data will be maintained in paper format in a secure location at UC Irvine. Only authorized individuals will have access to it. Research data will be imported into and stored electronically on the REDCap data management system.

Data Retention
Data will continue to be collected on patients for 12 months after their surgeries. Since the data includes personal health information, per protocol, it will be retained for a period up to six years after the study is completed.

WHO WILL HAVE ACCESS TO MY STUDY DATA?
The research team, authorized UCI personnel, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

Any information derived from this research project that personally identifies you will not be released or disclosed by these entities without your separate written consent, except as specifically required by law. Research records provided to authorized, non-UCI entities will not contain identifiable information about you. Publications and/or presentations resulting from this study will not include identifiable information about you.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

Investigator Financial Conflict of Interest
No one on the study team has a disclosable financial interest related to this research project.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

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 suggestions, problems or concerns you may have about the study, please contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 141 Innovation Drive, Suite 250, Irvine, CA 92697.

What is an IRB? An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?
You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: As the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

_____ _____
Subject Signature **Date**

_____
Printed Name of Subject

_____ _____
Signature of Person Obtaining Informed Consent **Date**
(Individual must be listed on Page 1 of this consent)

_____
Printed Name of Person Obtaining Informed Consent

A witness signature is required on this consent form only if: (Researchers: check which one applies)

☐ Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐ The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐ The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐ The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

For the witness:
I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____

Witness Signature **Date**

(If no witness signature is required, this witness signature section of the consent form may be left blank).

_____

Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 141 Innovation Drive, Suite 250, Irvine, CA 92697.