Prospective Randomized Controlled Trial Comparing Resident Performance and Clinical Outcomes with Two Different Polypropylene Meshes for Laparoscopic Inguinal Hernia

NCT01825187

Informed Consent Form

Document Date: September 21, 2016

Place Randomization Sticker Here

Patient ID Sticker

New Hanover Regional Medical Center
Institutional Review Board

Patient Consent/Authorization Form

Prospective Randomized Controlled Trial Comparing Resident Performance and Clinical Outcomes with Two different Polypropylene Meshes for Laparoscopic Inguinal Hernia

Principal Investigator:	William Hope, MD
Practice/Organization/Affiliation	South East Area Health Education Center Department of Surgery
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You are being asked to take part in a research study because you are having surgery to repair your hernia. Your study doctor will explain the study to you. Research studies only include people who choose to take part. Please take your time to make your decision about taking part in this study. You are encouraged to discuss your decision with your family and friends. You can also discuss it with your health care providers. If you have any questions, you can ask your study doctor or other members of the research staff.

This study has been reviewed for your safety by the New Hanover Regional Medical Center (NHRMC) Institutional Review Board (IRB). This Board has been established under the authority of the Food and Drug Administration (FDA) for the purpose of protecting the rights and well being of people recruited to participate in research activities. This Board looks at the risks and benefits of each study and receives updated information throughout the study to ensure your safety as a research participant.

Why is this study being done?

The purpose of this study is to compare the effectiveness of two meshes currently being used at New Hanover Regional Medical Center for the treatment of inguinal hernias (when soft tissue, which is usually part of the lower intestine, stick out through a weak point in the lower abdominal wall). Both of the meshes have been approved by the FDA and are a part of the usual treatment for the operation at NHRMC. Neither of the devices are considered investigational.

A secondary goal of the study is to evaluate the ease of use and time it takes surgical residents to place and perform the surgery using these two different meshes. This information may make it possible to determine if one mesh is easier for surgical residents to use during surgery and therefore take them less time to perform the procedure.

How many people will take part in this study?

Our goal is to enroll approximately five-hundred (500) people in this study at this location.

APPROVED KS
09/21/2016
IRB 1302-1

IRB Approval Date: 9/21/16

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

At your pre-operative appointment you will be asked to complete two questionnaires:

1. One will be a quality of life scale (Carolinas Comfort Scale) to gain information on your pain level and how you are managing your pain on a day-to-day basis.
2. The second questionnaire will be a Visual Analog Scale that allows you to demonstrate how much pain you are currently experiencing from your condition.

These surveys are routinely done and should take no longer than five (5) total minutes to complete. Information such as your age, sex, race, smoking and drinking history, along with your medications, allergies and previous surgeries will be documented from your medical record.

At the same pre-operative appointment, you will be randomized to either one of two study groups. Randomization means that you are put into a group by chance. You will have an equal chance of being placed in either group. The only difference between these two study groups is the brand of mesh being used. Currently, both of these meshes are being used by doctors at New Hanover Regional Medical Center.

Group 1: If you are randomized into this group, you will receive the Ultrapro mesh (manufactured by Ethicon).

Group 2: If you are randomized into this group you will receive the Bard 3d Max mesh (manufactured Bard).

On the day of surgery (during the operation), operative details will be documented including type of anesthesia (all patients will undergo general), surgery technique, type and side of hernia (direct or indirect), size of mesh used, type and number of tacks used to secure mesh, operative time, blood loss, urine output, and type and technique of closure. The operation will be performed using standard technique for laparoscopic (a surgery that uses a thin, lighted tube put through a cut (incision) in the belly) inguinal hernia repair. The patients in both groups will be thoroughly monitored by the medical staff for any signs and/or symptoms of adverse events.

When the surgery is complete, you will be asked to come in for a follow-up appointment between 1-2 weeks following the surgery. At this appointment, information such as length of hospital stay, complications from the surgery and whether or not the hernia returned will be recorded. You will also be asked to complete a quality of life scale (Carolinas Comfort Scale) and a visual analog scale (similar to the ones you took before surgery). This will allow Dr. Hope to access your pain level and how you are managing your pain on a day-to-day basis and to see how much pain you are currently experiencing from your condition. These scales may help to determine improvements from the surgery.

During your 1-2 week follow-up visit, you will be reminded of your six (6) month and one (1) year follow-ups. For your six (6) month and one (1) year follow-up, you will be contacted by telephone and/or be asked to return to the SEAHEC Physician's Office. If you are scheduled for a face-to-face visit, you will be called and reminded of the visit. You will not be charged for any of these services. At these visits, or over the phone, you will complete the same questionnaires (CCS and VAS) that you completed at your pre-op appointment. Information from these visits will also be collected from your medical record, such as length of hospital stay, complications from the surgery, and whether or not the hernia returned.

How long will I be in the study?

You are asked to participate in this study for 1 year following your surgery

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor or study staff if you are thinking about stopping or decide to stop. It is important that you tell the study doctor if you are thinking about stopping so any risks from the use of these meshes can be evaluated and the treatment may be stopped safely. Another reason to tell your study doctor is to discuss what follow-up care and testing could be helpful for you as well as other treatment options.

The study doctor may, without your consent, stop you from taking part in this study at any time if he believes it is in your best interest, if you do not follow the rules, or if the study is stopped for other reasons. The study doctor will tell you if your participation in the study ends early. You will also be told of any new findings that may develop during the study, which may change your willingness to participate in the study.

If you withdraw from the study, the data collected to that point might be included in the research findings to preserve research consistency. The study doctor will decide whether or not the data collected to the time of your withdrawal needs to be included.

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

Side effects associated with the use of the meshes are consistent with those typically seen following a normal surgery. These side effects include but are not limited to:

- Incision pain
- Fatigue,
- Bleeding or cramping
- Awareness of the mesh
- Stiffness in the groin

The risks associated with this study are only the known risks associated with having an inguinal hernia surgery.

You may have side effects while on the study. Everyone taking part in this study will be watched carefully for any side effects. However, doctors don't know all of the side effects that may happen. Side effects may be very mild or very serious. Your healthcare team may give you medicines to help lessen side effects. In some cases, side effects can be serious, long lasting, or may never go away. You should talk with your study doctor about any side effects that you may have while taking part in this study.

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

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. We do know that the information from this study will help doctors learn more about treatment for your condition and may be of benefit to future patients with the same condition.

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

Your other choices may include:

- Getting treatment or care for your inguinal hernia without being in a study.

Talk to your doctor about your choice before you decide if you will take part in this study.

Will my medical information be kept private?

The study doctor and research staff will do their best to make sure that the protected health information (PHI) in your medical record will be kept private. However, we cannot guarantee total privacy. Your PHI may be given out if required by law. If information from this study is published or presented at meetings, your name and other personal information will not be used. The information collected about you while participating in this study will be kept in a confidential file cabinet at South East Area Health Education Center (SEAHEC)'s Research Department and/or Dr. Hope's Office.

The PHI that we may use or disclose (release) for this research includes, all information in a medical record, results of physical examinations, medical history, findings during the surgery, information from pre and postoperative questionnaires, or certain health information indicating or relating to your hernia repair. As a result of this disclosure, printed copies of your records may be needed for research documentation.

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

- New Hanover Regional Medical Center (NHRMC) and it's IRB
- South East Area Health Education Center (SEAHEC)'s Research Department
- SEAHEC's Department of Surgery
- Food and Drug Administration (FDA)
- Office for Human Research Protections (OHRP)

Once your PHI has been disclosed to the above-listed agencies, the privacy laws may no longer protect it from further disclosure. Your consent to use or disclose the information as described in this consent expires at the end of this study.

Your PHI is needed to conduct the study in order to provide a complete comparison of the two meshes.

What are the costs of taking part in this study?

You and/or your health plan/insurance company will be responsible for covering routine care costs associated with doctor visits and the surgery. Check with your health plan or insurance company to find out what they will pay for. Participants in the study will be responsible for covering routine care costs and any co-pays associated with doctor visits.

There are no extra costs associated with this study. The six (6) month and one (1) year follow-up visits are not routine, therefore, you will not be charged for any of these services (both clinic and professional fees will not be billed to you or your insurance). For the 6 month and 1 year follow-up, you will be

contacted by telephone or be asked to return to the SEAHEC Physician's Office. Dr. Hope will discuss this information with you.

Will I get paid for taking part in this study?

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

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor if you feel that you have been injured because you took part in this study.

If necessary, you will get medical treatment if you are injured as a result of taking part in this study. You and/or your insurance company will be charged for this treatment. New Hanover Regional Medical Center is not financially responsible for treatment of side effects caused by the study treatments. You and/or your insurance company will be charged for continuing medical care and/or hospitalization.

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, but change your mind at any time, you may withdraw (revoke) your consent to participate and/or your authorization for us to use and disclose your personal health information. If you revoke your consent and/or authorization, you can no longer participate in the study.

No matter what decision you make, there will be no penalty to you and you will not lose any benefits to which you are entitled. Leaving the study will not affect your medical care at NHRMC. 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, William Hope, MD about any questions or concerns you have about this study at (910) 353-2516 ext. 233. For questions about your rights while taking part in this study, call the NHRMC Institutional Review Board Office at (910) 343-4621.

Where can I get more information?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time to obtain information about this clinical trial. The NCT number for this study is **NCT01825187.**

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Signatures

I have read or had read to me this consent/authorization form. I understand the information and have had my questions answered. I understand that I will be provided with a signed copy of this form. By signing this consent/authorization form, I agree to take part in this study and authorize the use and disclosure of my personal health information as described in this consent/authorization form. If I do not agree to sign the consent/authorization form, I understand that I will not be able to participate in the study and will need to talk with my doctor for other treatment options.

Subject:

Print Name_____

Signature_____ Date_____

If the subject is not competent to provide informed consent, this informed consent must be signed by the subject's legally authorized representative (an individual, judicial, or other body) who is authorized under law to consent on behalf of the subject to the subject's participation in the procedures involved in research.

Legally Authorized Representative (LAR) (if applicable):

*Print Name*_____ *Relationship*_____

*Signature*_____ *Date*_____

Principal Investigator: I have fully explained to the subject the nature, purpose, and risks of the treatments described above. I have answered any and all questions to the best of my ability.

Print Name_____

Signature_____ Date_____