Jefferson Office of Human Research
Informed Consent OHR-8
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Department: Surgery

Principal Investigator: Benjamin Phillips, MD

Study Title: Postoperative Gastric Point of Care Ultrasound (G-POCUS) in Abdominal Surgery: Can G-POCUS Guidance in Clinical Management of Gastrointestinal Recovery Lead to Better Outcomes?

Lay Title: Gastric Point of Care Ultrasound (G-POCUS)

General Information Section

Informed Consent

You are being asked to take part in a research study. Research is different from standard medical care and is done to learn something new.

Please read on to find out:

- The purpose of this research.
- How this research is different from standard medical care.
- The procedures involved.
- The risks.
- The possible benefits.
- The alternatives to taking part in this research.

You will have the opportunity to discuss this study with the research personnel. Use this information to decide if you want to take part in this research. This process is called informed consent.

Voluntary Participation

You do not have to take part in this research. It is your choice whether or not you want to take part. If you choose not to take part or choose to stop taking part at any time, there will be no penalty or loss of benefits that you would normally get.

Purpose

The purpose of this research is to determine if gastric point of care ultrasound (G-POCUS) can be used to help clinicians determine when to feed patients or when to insert or remove nasogastric tubes for patients recovering from colorectal or abdominal surgery. We also hope that using G-POCUS may help us predict certain complications after surgery, such as postoperative ileus (slowing of the bowels) or aspiration pneumonia (damage to your lungs caused by inhaling vomit).

How this Research is Different from Standard Medical Care

Currently, we make decisions on when to let patients eat after surgery or when to remove or replace nasogastric tubes based on patient interview and physical exam. These measures can be subjective, due to both patient and provider factors. G-POCUS presents a safe, easy to implement, cost-effective solution to assess gastric distention and motility, both of which give us important information on whether patients are experiencing postoperative ileus. We hope to show that using G-POCUS can significantly improve our clinical acumen in diagnosing issues with return of bowel function and consequently reduce the serious complications associated with impairment in bowel function return.

Number of Participants

About 128 people will take part in this research and Jefferson and about 128 in the whole study.

Duration

You will be in this research study for about one to five days, while hospitalized.

Procedures and Risks

It is important that you know the procedures and risks involved in this research. These will be discussed with you and are included in detail later in this form. Review the information carefully when making your decision to take part in this research.

Possible Benefits

You may personally benefit from taking part in this research by avoiding aspiration or ileus. Additionally, people in the future may be helped by what is learned in this study. Our hope is that the additional clinical information obtained from G-POCUS will let us make more informed decisions regarding bowel function and diet status, potentially leading to increased clinical accuracy.

Alternatives to Taking Part in this Research

You have other options than taking part in this study. The alternative to being in this study is to not take part.

Costs

You may have costs for participating in this study. This is discussed in detail later in this form.

Payment

You will not be paid for taking part in this study. If this research or the information or specimens you provide result in commercial profit, you will not receive any money from that profit.

Ending Study Early

There are a number of reasons you may decide or be asked to stop the study early (example: medical issues). You may also have to stop the study early even if you do not want to. You and the research personnel will discuss the reason if this becomes necessary.

New Information

New information may come out during this study. You will be given any new information that could change your decision to take part. You may ask to see the information collected about you, but not until the entire study is complete. You will be given any research results that could affect your health.

Detailed Information Section

Procedures

While you are in this study, you will have different procedures, tests and/or evaluations which are described below. Please note that additional tests and procedures may be needed to check on your health condition.

Eligible patients will have a G-POCUS on hospital day one. A portable ultrasound machine will be used to look at patient's stomachs and determine if they are full or empty. The procedure is safe, painless, and performed at bedside. It takes approximately 5 minutes to complete. Images will be obtained, measured, and catalogued. The results of the ultrasound will be used to make clinical decisions according to a care algorithm (i.e., remove/replace nasogastric tube (NGT),

advance/back down diet, etc.) Depending on the results of the ultrasound on the first day, patients may have additional G-POCUS exams performed on subsequent hospital days.

Risks

Taking part in this study involves certain risks. There may also be risks that are not known at this time. If you have any medical issues during this study, call the appropriate number in the contacts section of this form.

By implementing ultrasound into patients' evaluation, there is minimal additional risk. Ultrasound is a safe diagnostic tool that does not use ionizing radiation. The main risk associated with undergoing an ultrasound examination is mild discomfort at the ultrasound site.

Costs

You may have costs for participating in this study.

There will be no study related items or services billed to you or your insurance company. You may be responsible for other costs. There is no plan to pay you for lost wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s). If you receive a bill that you think is wrong, please contact the research personnel. You will be responsible to pay for your travel to and from the study site and other out-of-pocket expenses such as parking.

You should talk to your insurance carrier to find out what costs you will need to pay before taking part in this study. If you are a Medicare beneficiary and have opted for a Medicare Advantage plan to manage your health care needs, your out-of-pocket expenses may increase while you are on this study. Depending on your insurance carrier, some of the costs not covered by your insurance may be sizeable.

Financial assistance may be available under the institution's Charity Care Policy and Procedure.

Research-Related Injury

There is a possibility that you could have research-related injury, which is an illness or an injury that is directly caused by the study procedure. If you have a research-related injury, we will offer you reasonable and necessary care to treat injuries directly resulting from taking part in this research. Neither Jefferson nor the study will pay for costs associated with treatment of research-related injury or illness. These costs may be billed to your insurance. In addition, you will be responsible for any deductibles and co-payments required under your health plan and for any claims ultimately denied by your health plan. There are no plans for Jefferson to pay you or give

you other compensation for the injury. However, you are not prevented from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research. If you think you have been injured as a result of taking part in this research study, tell the research personnel as soon as possible. Please see the contact information in this consent form.

Privacy and Confidentiality: HIPAA Authorization

Information will be collected about you for this study. The information will be seen by the people involved with this research. Steps will be taken to protect your identity. But the information collected about you can never be 100% secure.

HIPAA (Health Insurance Portability and Accountability Act) – This is the law that protects your personal health information.

To do this study, we need to collect, use, and share your personal health information. This form will explain why your information is being collected, what information will be collected, and who will have access to it. By signing, you are giving us permission to use your information as described in this form.

We are committed to respecting your privacy and to keeping your personal health information confidential. Your personal health information includes the information in your health care records and information that can identify you. For example, personal information may include your name, address, phone number, social security number, and medical information. The personal health information that may be collected, used, and shared for this research includes:

- Information from your medical records
- Demographic information such as name, gender, birth date, ethnicity, medical history, and health care providers
- Physical examinations, procedures, tests, labs, your medical conditions, and medications you use
- Information collected about any research related injury
- Information about mental health, sexually transmitted diseases, HIV, AIDS, drug and alcohol use, genetic test results, and other sensitive information

Your personal information will be used by and shared with the following:

- Personnel at Thomas Jefferson University and its affiliates for the purpose of this research
- Research personnel at Rothman
- Institutional Review Boards (ethics committees that review research) including Thomas Jefferson IRB

- Health insurance providers
- Government Agencies like the Food and Drug Administration (FDA)
- Public health authorities who monitor such things as sexually transmitted diseases, HIV, AIDS, child abuse, as required by law
- Groups monitoring the safety of the study such as a data and safety monitoring committee
- Others as required by law

When your personal information is provided to some of the people listed, it may no longer be protected under the HIPAA privacy law. You can see your health care records at any time. However, generally you will not be able to see your study records or the study results until the study is completed. A copy of this signed form, information about this study, and the results of any study test or procedure may be included in your health records which may be seen by your insurance company and your health care providers.

This authorization does not have an expiration date. Please inform the investigator in writing if you want to end your permission to collect information/samples. Please note that anything already collected will still be used and you may not be able to continue in this study.

The information from this study may be published in scientific journals or presented at scientific meetings, but you will not be personally identified.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. 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.

Your private information and specimens, with the identifiers removed, could be used for future research studies or distributed to other researchers for future research studies without your additional permission.

Contacts

If you are having a medical emergency, call 911 or go directly to an emergency room. You should let emergency personnel or providers know that you are taking part in this study.

For Questions About:	Person or Office	Contact Information
The Study or Research Related Injury	Main Investigator: Dr. Benjamin Phillips Investigator: Dr. Caitlyn Costanzo	215-955-5869 215-955-5869
If you need to contact someone other than the study personnel about a concern or your rights as a research subject	Jefferson Center City Institutional Review Board (Ethics Committee)	215-503-0203 215-503-8966 215-955-4239
If you need to contact someone other than the study personnel about a concern or your rights as a research subject	Abington-Jefferson Health The Director of Risk Management at Abington-Jefferson Health Institutional Review Board (Ethics Committee) at Abington-Jefferson Health	 215-481-2209 215-481-7467

Signatures

Patient/Subject: By signing this form, you are agreeing that:

- You were given the opportunity to read this form.
- All of the information in this form was discussed with you by an investigator or other research personnel to your satisfaction.
- All your questions have been answered to your satisfaction.
- You were not pressured and you voluntarily agree to take part in this research.

Your Name	Your **Signature**	Date

Name of Person Obtaining/ Assisting with Consent	Signature of Person Obtaining/ Assisting with Consent	Date

By signing below, you the **investigator**, certify that you, a co-investigator, or other properly trained and qualified key personnel, reviewed the elements of consent with the study participant.

Name of Investigator	Signature of Investigator	Date

Name of Witness	Signature of Witness	Date

(Witness required if the only language the subject speaks and understands is English, but the subject cannot read English, or if the subject is blind or cannot physically sign the consent form.)

☐ **Copy of Signed and Dated Consent Form Given to the Subject/Parent/LAR**

Optional Teach-Back Questions – These questions can be asked to help ensure that the patient understands the study.

☐ Check this box if these questions were reviewed with the patient.

We have gone over a lot of information. I would like to ask you a few questions to make sure I have done a good job explaining the study to you.

1. In your own words, please answer these questions about this study:
    a. Why are we doing this study (what are we trying to learn)?
    b. What things (including tests and procedures) will you have to do in this study?
    c. What are some of the risks of being in this study?
    d. What is the benefit of being in this study?
    e. How will being in this study be different than usual medical care?
    f. How long will you be in this study?
2. Taking part in this study is voluntary. What does that mean to you?
    a. If you don't want to be in this study, what are your other choices?
    b. What will happen if you chose not to be in this study?
3. What will we do to make sure your information remains confidential?
4. What other questions do you have about this study?