Informed Consent Form

TITLE: BEFAST (Bubble-Enhanced FAST) for the Evaluation of Solid Organ Injury in Hemodynamically Stable Blunt Abdominal Trauma

NCT NUMBER: NCT05025449

IRB APPROVAL DATE: July 19, 2023

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 267 people who are being studied at Emory.

Why is this study being done?

This study is being done to answer the question: Does the use of ultrasound contrast improve the ability of the ultrasound exam to detect injury to abdominal organs (liver, spleen, pancreas, kidneys)? Ultrasound is an imaging test that, unlike CT scan, allows doctors to examine your organs without the use of ionizing radiation. You are being asked to be in this research study because you are a patient who might have suffered injury to your abdominal organs.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for 1 study visit. The researchers will ask you to do the following: US exam of abdomen with and without ultrasound contrast. ALL of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question: Does the use of ultrasound contrast improve the sensitivity of the exam for detecting injury to the liver, spleen, kidneys, pancreas?

What are the risks or discomforts I should know about before making a decision?

The study will take time and may not benefit you. The contrast-enhanced ultrasound exam that is being tested may not work any better than regular care, and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include headache, nausea, dizziness, flushing, allergic reactions, shortness of breath, back, kidney, or chest pain, hypertension, hypotension, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the “What are the possible risks and discomforts?” section of this document.

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate. Patients not joining the study will receive usual trauma care which may include a non-contrasted FAST exam (limited ultrasound of abdomen and chest).

Costs
You WILL NOT have to pay for any of the study procedures, in particular those that are not covered by your medical insurance. The study will not pay for usual care.

There is more information in the cost section below.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

Emory University and Grady Health System
Consent to be a Research Subject / HIPAA Authorization

Title: BEFAST (Bubble-Enhanced FAST) for the Evaluation of Solid Organ Injury in Hemodynamically Stable Blunt Abdominal Trauma

IRB #: 00100619

Principal Investigator: Laura Oh, MD, Emory School of Medicine, Department of Emergency Medicine

Sponsor: Department of Defense

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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 is the purpose of this study?
The purpose of this study is to see if using contrast (medication put through your IV) with ultrasound helps identify injury to your liver, kidney, spleen, or pancreas better than ultrasound that does not use contrast. The study will take place at Grady Memorial Hospital. A single ED visit is the expected duration of participation. The ultrasound study itself will take 5-10 min and will not delay standard emergency services. We will be enrolling 267 patients. The study will use an ultrasound contrast agent called Lumason. Lumason is not FDA approved for the purpose it is used in the study (trauma evaluation), but it is FDA approved for use in other applications, such as looking at heart function and liver lesions in adults and looking at bladder reflux in children.

What will I be asked to do?
During your emergency department stay we will do 2 ultrasound exams. Normally during a trauma evaluation for abdominal pain you would get one ultrasound study without contrast. If you participate in our study we will do one additional ultrasound study that is estimated to take around 5-10 minutes. We will take video clips of your liver, kidney, spleen, and pancreas with the ultrasound machine. The addition of contrast to the study is for research purposes only although if we see an injury we will notify your treating physician.

How will contrast agent be provided?
The contrast agent that will be administered through your IV that will be dispensed by the pharmacy and delivered to the principal investigator or study team member. Ultrasound contrast is delivered through the use of microbubbles that contain the contrast agent. Unlike CT contrast, ultrasound contrast does not harm kidneys. People who are allergic to CT contrast are not necessarily allergic to ultrasound contrast. US contrast does not expose you to radiation. The principal investigator or health care providers on his/her research team will provide the medicine to you. If you have questions about the medicine, you should ask the principal investigator or study nurse.

Who owns my study information and samples?
If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?
There may be side effects from the study drug or procedures that are not known at this time.

Ultrasound Procedure Risks:
Ultrasound risks are minimal – there is no use of ionizing radiation.

The most common risks and discomforts expected in this study from use of ultrasound are:
Discomfort from cold ultrasound gel.

Contrast Risk
The use of ultrasound contrast also has minimal risk based on previously published research.
The less common risks and discomforts expected in this study are: (6 patients out of 30,222)
Headache, nausea, dizziness, flushing, back pain, kidney pain, chest pain, shortness of breath, hypertension, mild allergic reactions
Rare but possible risks include: hypersensitivity to contrast resulting in low blood pressure (2 patients out of 30,222 patients)

If you are a woman: to protect against possible side effects of the study drug, women who are pregnant or nursing a child may not take part in this study. Pregnant women will be taken out of the study.

If you are a man: the effect of the study drug on sperm is not known.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. This study is designed to learn more about the ability of ultrasound to pick up injuries to liver, kidney, spleen, pancreas, when enhanced with the use of contrast. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will get $25.00 gift card for your participation in the study, to compensate you for your time and effort whether or not the study is completed. The study will not pay for usual care.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. You will get evaluated by the emergency medicine team who may order labs or imaging as needed. You do not have to be in this study to be treated for abdominal trauma.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you) may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data. Study subjects are not able to request destruction of images at a later date once they have been de-identified.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Medical Record

If you have been an Emory and Grady Health System patient before, then you already have an Emory and Grady Health System medical record. If you have never been an Emory and Grady Health System patient, you do not have one. An Emory and Grady Health System medical record will be made for you if an Emory and Grady Health System provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Grady Health System medical record you have now or any time during the study.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: results of your contrast-enhanced ultrasound exam.

Tests and procedures done at non-Emory and Grady Health System places may not become part of your Emory and Grady Health System medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you believe you have become ill or injured from this research, you should contact Dr. Laura Oh at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory and Grady Health System will help you to get medical treatment. Neither Emory, Grady Health System nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory, Grady Health System and the sponsor have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory and Grady Health System, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory and Grady Health System employee. “Negligence” is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

GHS Disclaimer

We will give you emergency care if you are injured by this research. However, Grady Health System and Emory have not set aside funds to pay for this care or to compensate you if a mishap occurs. If you believe you have been injured by this research, you should contact Dr. Laura Oh (Phone: [redacted])

We will treat you in the emergency department and admit or refer for followup to a primary care team or appropriate specialty clinic as needed.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under “injury” as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. If you wish to leave the study, please contact Dr. Laura Oh at [redacted]

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study.
- Emory and Grady Health System may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Grady Health System offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Grady Research Oversight Committee, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Food and Drug Administration
    - Public health agencies.

  - Research monitors and reviewer.
  - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.
- This is a Department of Defense (DoD) funded project. Please be advised that the DoD may also have access to your records.

Expiration of Your Authorization
Your PHI will be used until this research study ends. At that time, we will delete identifiers linking your participation to study data.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: [redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
Contact Laura Oh at [redacted]

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory University Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.

- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Patient Rights
If you are a patient receiving care from the Grady Health System and you have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

Name of Subject

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY WITNESS IN THE EVENT PATIENT IS NOT PHYSICALLY ABLE TO SIGN

Please **print** your name, **sign**, and **date** below if you witnessed the patient consenting to the research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep. Please do not fill in any of the subject's fields above.

Name of Witness

Relationship to Patient (e.g. spouse, friend, nurse)

Signature of Witness (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion **Date** **Time**