A randomized controlled trial of metoclopramide versus placebo during gastrojejunostomy tube placement for facilitating guidewire advancement through the pylorus

Protocol Identifying Number: Pro00081892

Principle Investigator: James Ronald, MD PhD

Funded by: Duke Radiology Putman Seed Fund

Informed Consent Form
September 23, 2017

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
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You are being asked to take part in this research study because your primary care team has requested you receive a gastrojejunostomy feeding tube be placed by the Duke University Department of Interventional Radiology. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. James Ronald will be your doctor for the study and be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine if receiving a one-time dose of the drug metoclopramide (a Food and Drug Administration approved medication commonly used to help the stomach and intestines move as they normally do during digestion) prior to the gastrojejunostomy tube placement procedure allows the procedure to be performed more efficiently, thus reducing the radiation dose to you during the procedure and reducing the time that the procedure takes.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 110 people will take part in this study at Duke University Hospital.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form.

You will be randomly assigned (like the flip of a coin) to a one-time dose of either the active drug (metoclopramide) or a placebo, which is an inactive substance (saline), approximately 15 minutes prior to undergoing the actual procedure. You have a 50 percent chance of receiving study drug. The gastrojejunostomy tube placement procedure will then be timed, with times recorded at various steps of the procedure. The cumulative radiation exposure at each step will also be recorded.

Participation in this study is completely voluntary. Refusal to participate will not change your treatment plan, and will not incur any penalty or loss of benefits that you are otherwise entitled to. If you do not sign this consent form, you will continue to receive care, but not as a part of this study.

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HOW LONG WILL I BE IN THIS STUDY?

Participation in this study will occur only during the gastrojejunostomy tube placement procedure. At the completion of the gastrojejunostomy tube placement procedure, your participation in the study will be complete. No long term follow up will be required from you.

WHAT ARE THE RISKS OF THE STUDY?

As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider, if you choose.

Metoclopramide may cause some, all, or none of the side-effects listed below. These side effects are more common with repetitive use of metoclopramide and are rare in single doses.

More likely

- Feeling restless, sleepy, tired, dizzy, or exhausted
- Headache
- Confusion
- Trouble sleeping

Less Likely

- Abnormal muscle movements
- Uncontrolled spasms of your face and neck muscles, or muscles of your body, arms, and legs (dystonia)
- Neuroleptic Malignant Syndrome (NMS). NMS is a very rare but very serious condition that can happen with metoclopramide. Symptoms of NMS include: high fever, stiff muscles, problems thinking, very fast or uneven heartbeat, and increased sweating.
- Parkinsonism. Symptoms include slight shaking, body stiffness, trouble moving or keeping your balance. If you already have Parkinson's disease, your symptoms may become worse while you are receiving metoclopramide.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may be direct medical benefit to you. There is the possibility that your procedure will be completed in a shorter amount of time than usual. We hope that in the future the information learned from this study will benefit other people needing gastrojejunostomy tubes.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

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Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law or for your care, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept securely at DUHS.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

Some information collected about you only for this research study may be kept in a research study record separate from your medical record, and some research information may also be part of your medical record. You will not have access to this research information until the end of the study. However, it will be available to your physicians if needed for your care.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

WHAT ARE THE COSTS?

There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. James Ronald at 919-684-7299 during regular business hours and at 919-970-7930 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

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You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke.

If you stop being part of this study, the study doctor or one of the staff members will talk to you about any medical issues regarding the stopping of your participation.

If you do decide to withdraw, we ask that you contact Dr. James Ronald in writing and let him know that you are withdrawing from the study. His mailing address is:

Department of Interventional Radiology
Duke University Medical Center
North Hospital, Box 3808
Durham, NC 27710

Your participation also may be stopped by the study doctor without your consent if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. James Ronald at 919-684-7299 during regular business hours and at 919-970-7930 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have

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been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____ _____ _____
Signature of Subject Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time

If the subject is unable to consent, a legal representative may provide consent:

I am the representative of the subject and am acting on behalf of the subject. I am not aware of any factor that might create a conflicting interest for me in this role (for example, something that might bring me personal benefit). I consent to the subject's participation in this study.

_____ _____ _____
Signature of Legal Representative Date Time

_____
Relationship to Subject