

Mercy Health Youngstown
Informed Consent Form for

Comparison air versus carbon dioxide insufflation in single balloon anterograde enteroscopy

NCT 03811522

1/11/2019

Informed consent

Title of Research Proposal: Comparison air versus carbon dioxide insufflation in single balloon anterograde enteroscopy

Principal Investigator: Thomas Geisler

Purpose of Research: I have been informed that this study will look at the level of discomfort you feel after undergoing the procedure with different gases involved in inflating the small bowel. This research allows the investigators to compare CO₂ vs air used to inflate the bowel. Whether you receive CO₂ or air will be determined at random, a process that is like flipping a coin. Investigators are looking at symptoms of belly pain, nausea, and fullness after the endoscopic procedure.

Randomization process: There will be approximately 50 to 80 patients enrolled in this study. Randomization will be performed at time of scheduling the procedure using a sealed envelope system.

Procedure: I understand that I will be asked to participate in an after procedure survey on the level of discomfort I'm feeling at 15 minutes, 30 minutes and 1 hour after procedure. I will also be given a survey to take home and return at 1 day after procedure. This survey will be mailed back to the researcher in the prepaid addressed envelope provided to me. The survey will ask about level of belly pain, nausea, and fullness. Nausea and fullness will be asked on a zero-to-ten scale. Zero is no symptoms and ten is the worst of your life. The belly pain will be measured on a horizontal line. No belly pain will be at the bottom of the line and more your pain is the higher you will mark on the line.

Risks and Discomforts:

I understand that the standard risks for single balloon endoscopy consist bleeding, perforation (<1%), pancreatitis (<1%), ileus (<1%), and also those standard risks involved with general anesthesia. I also understand the risk for carbon dioxide insufflation could entail respiratory depression due to carbon dioxide retention, gas embolism (<0.6%), and potentially unforeseeable risks which may also be involved.

Benefits: I understand that my participation in the study will help us better understand how to inflate the small bowel during this procedure to reduce the amount of discomfort you feel afterwards. I also understand that there may be no direct benefit to participating in this study.

Confidentiality: I understand that medical information produced by this study will become part of my medical record and will be subject to the confidentiality and privacy regulations of Humility of Mary Health Partners. Information of a sensitive and personal nature will not be part of the medical record, but will be stored in the investigator's research file and identified only by a code number. The code key-connecting name to numbers will be kept in a separate secure location. If the data are used for publication in the medical literature or for teaching purposes, no names will be used, and other identifiers, such as photographs and audio- or videotapes, will be used only with my special written permission. I understand I may see the photographs and videotapes and hear the audiotapes before giving this permission. If an investigational drug or device is to be studied, then

I understand that the Food and Drug Administration and the industrial sponsor are permitted to have access to my medical record and to the data produced by the study, for audit purposes. However, they are required to maintain confidentiality.

Request for More Information: I understand that I may ask more questions about the study at any time. Contact Thomas Geisler D.O. email geislet@gmail.com or by phone at 716.640.4764. A description of this clinical trial will also be available on <http://www.clinicaltrials.gov> as required by U.S. law. This website will not include any information that identifies me as a participant. At most, the website will include a summary of the results. This website is able to be accessed at any time.

Refusal or Withdrawal of Participation: I understand that my participation is entirely voluntary and that refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled, and that I may discontinue or withdraw from participation in this study at any time without penalty or loss of benefits to which I am otherwise entitled. Should I decide to withdraw I understand and I should still discuss the need for care with my doctor. I understand that the Primary Investigator is also able to withdraw a participant without their consent to promote the patient's well-being. Should I elect not to participate in the study, I understand that I will receive the standard of care.

Funding and costs: I understand that there are no financial incentives for the physicians or for Mercy Health Youngstown to conduct the study and that participation in this study will not result in any financial compensation. I understand that there will be no additional cost to care with my participation in this study, however, participation may incur cost for any injury caused by research study.

Additional:

I will receive a copy of this informed consent for my own records and understand that the Primary Investigator will also keep a copy of this consent on file. Should any significant findings be discovered by the Primary Investigator, the results will be discussed with me in a timely manner.

Addendum to Informed Consent Form:
Authorization to Use and Disclose Personal Health

A federal government rule has been issued to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality of your personal health information. Your personal health information is information about you that could be used to find out who you are. For this research study, this includes information in your existing medical records needed for this study and new information created or collected during the study.

This Authorization explains how Mercy Health Youngstown, LLC will use or disclose your health information for this research study. It also describes your privacy rights, including your right to see your personal health information.

You understand that this authorization is voluntary and you may refuse to sign it. By signing the consent document for this study, you will give permission ("authorization") for the use and disclosure of your personal health information that are described in this Authorization. If you do not want to allow these uses, you must not participate in this study. If you agree to participate in the research study, your personal health information will be used and disclosed in the following ways:

- The study doctor and staff will use your medical records and information created or collected during the study to conduct the study.
- The study doctor and staff will send your study-related health information to the sponsor of the study and its representatives (“sponsor”). Because the sponsor conducts business related to clinical research in many countries around the world, this may involve sending your health information outside of the United States. Other countries may have privacy laws that do not provide the same protections as the laws in this country. However, the sponsor will respect the terms of this Authorization in all countries.
- Your health information sent by the study doctor to the sponsor does not include your name, address, social security number, or other information that *directly* identifies you. Instead, the study doctor assigns a code number to your health information and may use your initials. Some of your health information sent to the sponsor may contain information that could be used (perhaps in combination with other information) to identify you (eg, date of birth). If you have questions about the specific health information that will be sent to the sponsor, you should ask the study doctor.
- The sponsor will use your health information for research purposes to support the scientific objectives described in the consent document and the process of getting regulatory approvals for its drugs.
- The sponsor may add your health information to data from other studies in research databases so that it can study how to improve measures of safety and effectiveness, study other therapies for patients, develop a better understanding of diseases, or improve the design of future clinical trials.
- Your health information, either alone or combined with health information and study data from other studies, may be shared with regulatory authorities in the United States and other countries, doctors at other institutions participating in the study, the ethical review board overseeing this study, and laboratories and other individuals and organizations that analyze your health information in connection with this study.
- Health information that does not directly identify you may be published in medical journals or shared with others as part of scientific discussions.
- Your original medical records, which may contain information that directly identifies you, may be reviewed by the sponsor, the ethical review board overseeing this study, and regulatory authorities in the United States and other countries. The purpose of these reviews is to assure the quality of the study conduct and the study data, or for other uses authorized by law.
- The sponsor works with business partners in drug development. The sponsor may share your health information with these business partners, but only if the business partners need the information as a part of this work with the sponsor, and only if the business partners signs a contract that requires it to protect your health information in the same way as the sponsor.
- The sponsor will not disclose personal health information to insurance companies unless required to do so by law, or unless you provide separate written consent to do so.
- Your medical records and other health information may be held and processed on computers.

Your personal health information disclosed under this Authorization may be subject to redisclosure by the recipient(s) and no longer be protected under the HIPAA privacy rule. Mercy Health Youngstown, LLC may not condition your treatment or care on whether or not you sign this Authorization.

You have the right to see and copy your personal health information related to the research study for as long as this information is held by the study doctor or research institution. However, to ensure the scientific integrity of the study, you will not be able to review some of the study information until after the study has been completed.

You may cancel your authorization at any time by providing written notice to the Department of Research at St. Elizabeth Youngstown Hospital, 1044 Belmont Avenue, Youngstown, OH, 44501. You understand that your revocation will not have any affect on any actions with respect to your health information taken before your revocation. Your authorization for the uses and disclosures described in this Authorization does not expire.

Research Subjects Rights: I understand that if I have any questions regarding my rights as a research subject, I may ask the Chairperson of the Mercy Health Youngstown IRB (Institutional Review Board), Dr. Barreiro at (330) 480-3610.

Note: Unless additional arrangements have been made, all Consent Forms must include the following waiver: I agree that all risk to me have been explained to my satisfaction and I understand that no compensation is available from Mercy Health Youngstown for any injury resulting from my participation in this research.

Signature of subject/patient

Date

Witness to Signature

Date