Title: Is end tidal CO2 level elevation during upper endoscopy with CO2 gas insufflation physiologically significant?

NCT Number: NCT04541667

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CONSENT FORM

Title of this Research Study

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Hospital & Medical Center (CH&MC).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

Purpose

We are inviting you to participate in this research study because you have been scheduled for an endoscopic procedure (Upper endoscopy, upper endoscopy with colonoscopy, percutaneous endoscopic gastrostomy (PEG) tube placement or PEG tube change). The purpose of this research study is to see if carbon dioxide (CO_2) is a safe way of inflating the stomach/intestine during endoscopy instead of air. Many studies in adults and three studies in children suggest that CO_2will cause less abdominal discomfort and bloating than air. There is currently no standard of care on the gas to use for insufflation during endoscopy in our center, and this is left to the discretion of the doctor performing the procedure.

Methods

If you choose to take part in the study, you will be randomly assigned (like flipping a coin) to either the air group or carbon dioxide group. You and your doctor will not know the group to which you are assigned. Your involvement in the study will only include a random assignment. We will collect information on your medical history such as your age, the type of procedure being performed, the reason for the procedure, any other risk factors you may have, your weight. We will also collect information on your vital signs before and during the procedure. We may ask you a few questions later on if you experienced any complications from the procedure or anesthesia. We will not collect any other follow up information. Your odds of being in

the study group (carbon dioxide) vs the standard group (air) is 50/50 (a 1 in 2 chance).

Risks
Risks of the study include abdominal discomfort, bloating and trouble breathing. In a study in children that used carbon dioxide gas for inflating the stomach and small intestines with carbon dioxide gas during upper endoscopy in children who had moderate sedation; there was an associated increase in the level of carbon dioxide in the body measured by one device that was not seen in a second device. This has only been shown in one study in children. There is also a possible risk of loss of confidentiality on information regarding you; however, we will do our best to guard against this.

Benefit
In two studies in children where carbon dioxide used for inflating the large intestines and small intestine; more children in the carbon dioxide group had less pain than the air group. In the third study; children in the carbon dioxide group had less bloating than the air group. We hope to be able to learn whether the use of carbon dioxide is as safe as air. We hope that, in the future, other children might benefit from this study because of knowledge gained in determining whether carbon dioxide is safe.

Alternatives
Instead of being in this study, you can choose not to participate and we will use air or carbon dioxide (if it is available) for inflation during your procedure.

Why are you being asked to be in this research study?
You are being asked to be in this study because you are between 6 months old to ≤ 19 years old and you have been scheduled for an endoscopic procedure (Upper endoscopy, upper endoscopy with colonoscopy, percutaneous endoscopic gastrostomy (PEG) tube placement or PEG tube change). About 200 subjects will participate in this study conducted only at CHMC. If you are pregnant, nursing an infant, during this study, you may not be in this study.

What is the reason for doing this research study?
During endoscopy, we usually use air to inflate the stomach and intestines so that we can see clearly and move the scope around. Many studies in adults and three studies in children suggest that CO_2causes less abdominal discomfort and bloating than air. We do not know if CO_2use during upper endoscopy is safe for subjects. This

research is trying to see if $CO^2$is safe if used during upper endoscopy.

What will be done during this research study?
If you choose to take part in the study, you will be randomly assigned (like flipping a coin) to either the air group or carbon dioxide group. You and your doctor will not know the group to which you are assigned. Your involvement in the study will only include your random assignment. Your odds of being in the study group (carbon dioxide) vs (air) is 50/50 (a 1 in 2 chance).

We will also collect information from your medical records, such as your age, the type of procedure being performed, the reason for the procedure, any other risk factors you may have, your weight. We will also collect information on your vital signs before and during the procedure. We may ask you a few questions later on if you experienced any complications from the procedure or anesthesia. We will not collect any other follow up information.

What are the possible risks of being in this research study?
Risks of the study include abdominal discomfort, bloating and trouble breathing. In a study in children that used carbon dioxide gas for inflating the stomach and small intestines with carbon dioxide gas during upper endoscopy in children who had moderate sedation; there was an associated increase in the level of carbon dioxide in the body measured by one device that was not seen in a second device. This has only been shown in one study in children.

There is also a possible risk of loss of confidentiality of your information. However, we will do our best to guard against this.

It is possible that other rare side effects could occur which are not described in this consent form. It is also possible that you could have a side effect that has not occurred before.

What are the possible benefits to you?
It is possible that if carbon dioxide gas is used in inflating your stomach and intestines; that you may have less pain than if air is used. However, you may not get any benefit from being in this research study.

What are the possible benefits to other people?
We hope that, in the future, other subjects might benefit from this study because of knowledge gained in determining whether carbon dioxide is safe.

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to participate.

What will being in this research study cost you?
While there is no cost for participating in the research, the standard of care procedures will be the responsibility of you or your insurance

Will you be paid for being in this research study?
You will not be paid to be in this research study.

Who is paying for this research?
This research is being paid for by the Department of Gastroenterology.

What should you do if you are injured or have a medical problem during this research study?
Your welfare is the main concern of every member of the research team. If you are injured or have a medical problem or some other kind of problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form. Emergency medical treatment for this injury or problem will be available at the Nebraska Medical Center. If there is not sufficient time, you should seek care from a local health care provider.

The Institution has no plans to pay for any required treatment or provide other compensation. If you have insurance, the insurance company may or may not pay the costs of medical treatment. If you do not have insurance, or if the insurance company refuses to pay, you will be expected to pay for the medical treatment.

Agreeing to this does not mean you have given up any of your legal rights.

How will information about you be protected?
You have rights regarding the protection and privacy of your medical information collected before and during this research. This medical information is called "protected health information" (PHI). PHI used in this study may include your medical record number, address, birth date, medical history, the results of physical exams, blood tests, x-rays as well as the results of other diagnostic medical or research procedures. Only the minimum amount of PHI will be collected for this research. Your research and medical records will be maintained in a secure manner.

Who can see information about you?
By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at the Institution.

Your PHI will be used only for the purpose(s) described in the section "What is the reason for doing this research study?"

You are also allowing the research team to share your PHI, as necessary, with other people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that the subject's information may be shared with these groups:
    - The HHS Office for Human Research Protections (OHRP)
- The HIPAA Privacy Rule requires the following groups to protect the subject's PHI:
    - The subject's health insurance company

You are authorizing us to use and disclose your PHI for as long as the research study is being conducted.

You may cancel your authorization for further collection of your PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.

At some time in the future, we may take the identifiers off the information. It is possible that this information without identifiers could then be used for other research studies by us, or by another investigator, without asking you for permission.

How will results of the research be made available to you during and after the study is finished?

Information obtained in the course of the research that will not be shared with you is [the type of gas used in insufflation during the procedure or the gas used in inflating your stomach and intestines]. By signing this authorization, you are temporarily giving up the right to see this research-related information while the research is going on. You will be able to see this information if you wish after the research is completed.

In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address

Division of Pediatric Gastroenterology
Chinenye R Dike
Children's Hospital & Medical Center
8200 Dodge Street,
Omaha NE 68114

A description of this clinical trial will be available on 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.

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or the Institution. Your doctor will still take care of you. You will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop your participation in this research (withdraw) at any time by contacting the Principal Investigator or any of the research staff. Deciding to withdraw will otherwise not affect your care or relationship with the investigator or this institution. You will not lose any benefits to which you are entitled.

Any research data obtained to date may still be used in the research.

Will you be given any important information during the study?
You will be informed promptly if the research team gets any new information during this research study that may affect whether you want to continue being in the study.

What should you do if you have any questions about the study?
You have been given a copy of*"What Do I Need to Know Before Being in a Research Study?"*If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

What are your rights as a research participant?

You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights or complaints about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463.
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
    - Telephone: (402) 559-6941
    - Email: unmcrsa@unmc.edu

Documentation of informed consent

You are deciding whether to be in this research study. Signing means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects You have had your questions answered.
- You have decided to be in the research study.
- You have been told you can talk to one of the researchers listed below on this consent form if you have any questions during the study.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject_____Date_____

Signature of Parent_____Date_____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person Obtaining Consent_____Date_____

Authorized Study Personnel

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Secondary
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degree: MD

* Shukry, Mohanad
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degree: MD/NE

Participating Personnel
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degree: DO

* Kusek, Mark
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degree: MD

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