University of Nevada, Reno

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Institutional Review Board
Approved on: December 21, 2017

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University of Nevada, Reno
Consent Form for Biomedical Research

Title of Study:	*Simethicone pretreatment with low-volume Polyethylene Glycol-3350 and Bisacodyl in an effort to improve bowel wall visualization*
Principle Investigator:	Eric Osgard M.D. 775-329-4600
Co-Investigators / Study Contact:	Dr. Mohit Rishi contact number: 715-803-8393 (Primary contact) Dr. Jaskarin Kaur contact number: 558-387-7725 Dr. Abubaker Abdalla contact number: 312-690-1307 Molly Svensdsen contact information: 541-647-8721 Nicholas Manasewitsch contact information: 702-439-8843 Dr. James T. Doyle contact information: 775-329-4600
Study ID Number:	1139179
Sponsor:	N/A

Introduction

You are being invited to participate in a research study. Before you agree to be in the study, read this form carefully. It explains why we are doing the study; and the procedures, risks, discomforts, benefits, and precautions involved.

At any time, you may ask the study doctor, study coordinator, or one of the researchers to explain anything about the study that you do not understand.

It's important you are completely truthful about your health information and your eligibility to be in the study. If you are not truthful, you may be harmed by being in the study.

You do not have to be in this study. Your participation is voluntary. If you do not agree to participate, you will receive the care you would have received if the study was not taking place. Take as much time as you need to decide. If you agree now but change your mind, you may quit the study at any time. Just let the study doctor or one of the researchers know you do not want to continue.

Why are we doing this study?

We are doing this study to find out whether the use of Simethicone will improve imaging during your colonoscopy procedure. Your gastroenterologist will make this determination during your planned procedure. This is a safe compound and is the main ingredient in over the counter medications such as GasX and infant gas relief drops.
Benefits of research cannot be guaranteed but we hope that it improves visualization during the procedure.

Why are we asking you to be in this study?

We are asking you to be in this study because you are an adult eligible for a diagnostic colonoscopy.

How many people will be in this study?

We expect to enroll 125 participants at GI consultants North office. 250 participants will be enrolled at all sites associated with GI Consultants

What will you be asked to do if you agree to be in the study?

If you agree to be in this study you will be asked to:

a. Take contents of a vial containing either liquid Simethicone or a liquid inert placebo home and store it in a dry and cool place. You will need to mix the contents of this vial with your bowel preparation 1 day prior to the procedure.
b. After you receive your kit containing the contents of your bowel preparation, read the instructions provided carefully. Add the contents of the vial along with the contents of the bowel preparation in a container along with water. Mix or shake.
c. Drink the entire bowel preparation as per the instructions that came with the bowel preparation kit.

Study Design

After enrollment, you will be assigned to either a test group (simethicone group) or a non-test group (placebo group). Neither you nor your gastroenterologist will know the nature of your assignment. This is called double blinding and it ensures a higher standard of scientific quality. This also prevents bias (prejudice or favor). Also, we are placing participants in a test group to compare various effects of simethicone to participants who do not receive this medication. Assignment is completely randomized to ensure fair distribution. Each participant has an equal chance to be assigned in either group.

All data will be gathered from your planned colonoscopy and no extra procedures or tests will be done for this research. Also, no follow up is necessary for the purposes of this research. One of the members of the team may call you the day before your colonoscopy as a gentle reminder to take the medication with your bowel preparation. Simethicone is considered a safe over the counter medication with no reported side effects. As with all medications there is a minimal risk of a hypersensitivity reaction to simethicone, however very rare. This study does not carry significant risks other than the risks associated with getting a colononoscopy. Your gastroenterologist will explain these risks. Keep in mind he/she will reserve the right to take you out of the study should any concerning health problems arise which require you not to participate or for any other concerns that may come up.

How long will you be in the study?

Except for the time that you spend hearing about and consenting to be in the study (10-20 minutes), no additional time will be required from you other than the normal time commitment involved in having a colonoscopy. The study will be performed on the day of your scheduled colonoscopy, and no further follow-up for the research will be required from you after that.

What are your choices if you do not volunteer to be in this research study?

If you decide not to be in the study, your other choices may include:

- Getting no treatment.
- Getting standard treatment for your condition without being in a study.
- Getting a different experimental treatment by taking part in another study.

What if you agree to be in the study now, but change your mind later?

You do not have to stay in the study. You may withdraw from the study at any time by calling one of the member of the research team.
If you leave the study early, we will ask you to not take the medication with your bowel preparation.

What if the study changes while you are in it?

If anything about the study changes or if we want to use your information in a different way, we will tell you and ask if you if you want to stay in the study. We will also tell you about any important new information that may affect your willingness to stay in the study.

Is there any way being in this study could be bad for you?

If you participate in this study, you may experience some side effects associated with colonoscopy preparation. These include excessively watery stools, nausea, vomiting, abdominal discomfort, or cramping. If these symptoms persist or get worse, stop taking the preparation and call your doctor or pharmacist.

What happens if you become injured because of your participation in the study?

In the event that this research activity results in an injury, treatment will be available. This includes first aid, emergency treatment, and follow-up care as needed. Care for such injuries will be billed in an ordinary manner to you or your insurance company.
We cannot promise you will benefit from being in this study.

Who will pay for the costs of your participation in this research study?

Researchers will pay for the additional supplementation of simethicone or placebo. You and/or your health plan/insurance company will need to obtain and pay for the bowel preparation.

You and/or your health plan/insurance company will need to pay for all of the other costs of caring for your condition while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no cost. Before you decide to be in the study, you should check with your health plan/insurance

company to find out exactly what they will pay for. Your insurance company or yourself are responsible for the cost of the bowel preparation.

Will you be paid for being in the study?

You will not receive any payment for being this study.

Who will know that you are in in this study and who will have access to the information we collect about you?

The researchers, University of Nevada, Reno Institutional Review Board, and US Department of Health and Human Services (DHHS) will have access to your study records.
A description of this clinical trial 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.

How will we protect your private information and the information we collect about you?

We will treat your identity with professional standards of confidentiality and protect your private information to the extent allowed by law. We will do this by...

Personal information will be replaced with codes. The list linking participant names and the codes will be stored securely and separately from the research data.

The research data will be stored on paper under locked file cabinet, in a facility with password-protected access, password protected Electronic Portable Device, and/or in a password protected laptop in an encrypted file.

We will not use your name or other information that could identify you in any reports or publications that result from this study.

Who can you contact if you have questions about the study or want to report an injury?

At any time, if you have questions about this study or wish to report an injury that may be related to your participation in this study, contact

Research contact Information:
Dr. Mohit Rishi contact number: 715-803-8393 (primary)
Dr. Jaskarin Kaur contact number: 558-387-7725
Dr. Abubaker Abdalla contact number: 312-690-1307
Molly Svensdsen contact information: 541-647-8721
Nicholas Manasewitsch contact information: 702-439-8843
Dr. Eric Osgard contact information: 775-329-4600

Who can you contact if you want to discuss a problem or complaint about the research or ask about your rights as a research participant?

You may discuss a problem or complaint or ask about your rights as a research participant by calling the University of Nevada, Reno Research Integrity Office at (775) 327-2368. You may also use the online *Contact the Research Integrity Office* form available from the *Contact Us* page of the University's Research Integrity Office website.

Agreement to be in the study

If you agree to participate in this study, you must sign this consent form. We will give you a copy of the form to keep.

[redacted]
Participant's Name Printed

[redacted] 3/2/18
Signature of Participant Date

[redacted] 3/2/18.
Signature of Person Obtaining Consent Date