Consent and Authorization Form

Principal Investigator: Shelby Sullivan, MD
COMIRB No: 19-0278
Version Date: August 26, 2019

Study Title: *The effect of a gas-filled intragastric balloon for weight loss compared with a meal replacement weight loss program on gastric emptying, hormonal adaptation to weight loss, and hunger*

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

You are being asked to participate in this research study because you have initiated treatment with either the GF-IBD System Treatment (intragastric balloon system) or the My New Weigh program (MRP).

The disease obesity continues to be a major health issue in the US with over one third of the population having obesity (a body mass index >30 kg/m^2). Obesity causes other serious disease including diabetes, hypertension, high cholesterol and heart attacks. Obesity treatment or weight loss remains difficult to achieve. Several devices that are placed with an endoscope through the mouth or removed with an endoscope have been approved for use in the United States, including three intragastric balloon systems (2 fluid filled, 1 gas filled). These devices have lower risks than bariatric surgery and do not alter the anatomy of the stomach. Weight loss with all intragastric balloons is higher than lifestyle therapy or weight loss medications, but less than bariatric surgery. A few studies have investigated the mechanism of action of fluid-filled balloons on weight loss, these data suggest that the rate of food emptying from the stomach as well as the balloon taking up space in the stomach contributes to weight loss. However, no studies have investigated the mechanisms of action of gas filled intragastric balloons on weight loss.

There are 3 aims for this study. We will determine the effects of achieving 10% total body weight loss with either the gas filled intragastric balloon or a meal replacement program on: 1) the rate of food emptying the stomach, 2) the gut hormone response, and 3) hunger.

Your participation in this study will last 12 months.

Other people in this study

Up to *50* people from your area will participate in the study. This study is only being conducted at this site.

What happens if I join this study?

If you join the study, you will consent to undergo the following tests both before starting either the gas-filled balloon system treatment or the meal replacement program and when you reach 10% total body weight loss:

1. During screening to see if you are eligible for the study you will have a history and physical exam and complete two questionnaires:
    a. The Patient Health Questionnaire -9, which screens for depression
    b. The Questionnaire on Eating and Weight Patterns – 5, which screens for eating disorders
2. Gastric Emptying Study: After an overnight fast, you will report to the outpatient radiology center at the University of Colorado Hospital Anschutz Outpatient Pavilion at your scheduled time. You will eat a meal of scrambled egg substitute labeled with a tracer that can be seen on x-ray, toast, jam, and a 4 ounces of water. Images will be obtained before the meal, and at 30 minutes, 1 hour, 2 hours, 3 hours, and 4 hour after the meal. The test should take a total of 5 hours. You will then be discharged home
3. Mixed Meal Test: This test will occur within 7 days of the gastric emptying study. On a separate test day after an overnight fast, you will report to the Clinical Translational Research Center at the University of Colorado School of Medicine. An intravenous catheter or “IV” will be placed into a hand or forearm vein for blood draws. You will consume a meal over 15 minutes. Blood draws will be obtained before you eat the meal and at 15, 30, 60, 90, 120, 150, and 180 minutes after the meal. You will also fill out a questionnaire about hunger with each blood draw. The test should take 3.5-4 hours. You will then be discharged to home.

You also consent to allow the PI and study team to continuously monitor your weight loss progress so that we can repeat the studies when you reach 10% total body weight loss. This will entail weekly calls to review

weight loss and rate of weight loss. If you do not achieve a 10% weight loss by 6 months, you will be withdrawn from the study.

There will be a follow-up visit at 12 months to check weight.

What are the possible discomforts or risks?

Blood drawing and catheter insertion
Likely: The risk of blood drawing and intravenous catheter insertion include discomfort, bleeding, and/or bruising at the site of insertion.
Rare:

- Infection at the site of catheter insertion for blood drawing.
- If the IV catheter slips out of the vein, fluid could collect in your arm and cause swelling and discomfort.
- Feeling faint when the catheter is inserted

A total of 64 mL of blood will be drawn for the entire study.

Questionnaires (Patient Health Questionnaire, Questionnaire on Eating and Weight Patterns – 5, Visual Analogue Scale to Assess Hunger)
Rare: You may experience emotional discomfort when answering some questions in the questionnaires. If any particular question makes you uncomfortable, you may discuss its importance and the need to answer it with the study coordinator. If any particular question makes you uncomfortable, you do not have to answer it, but this may impact your participation in the study. You may also screen positive for uncontrolled depression or an eating disorder. If this occurs, your test results will be sent to your primary care physician and information on for mental health services will be provided. If this occurs, your test results will be sent to your primary care physician if you want, and information for mental health services will be provided.

Gastric Emptying Study
Likely: This study will expose you to radiation from the radioactive labeled food. Your natural environment has some radiation in it. It comes from the outer space, from soil, rocks, bricks and concrete, from some foods, and from radon gas, which is an invisible gas that seeps out of the ground. The amount of radiation that this procedure will give you is equal to <13% of the average radiation exposure to US adults annually.
Rare: allergic reaction to any meal component – please advise the study team if you have any allergies to any foods.

Confidentiality
There is a risk that people outside of the research team will see your

research information. We will do all that we can to protect your information, but it cannot be guaranteed.
To minimize this risk, as much personal health information (PHI) as possible will be removed, and only a unique number code and the data you provided will remain. The study may include risks that are unknown at this time.

What are the possible benefits of the study?
This study is designed for the researcher to learn more about the ways in which intragastric balloons help. This study is not designed to treat any illness or to improve your health. The benefits to you include knowing your rate of gastric emptying.

Who is paying for this study?
PI start-up funds are being used to pay for this study.
Dr. Sullivan received financial compensation as a consultant for Obalon Therapeutics, Inc., the manufacturer of the intragastric balloon being used in this study.

Will I be paid for being in the study?
You will be paid $400 for completion of all study testing. You will be paid $100 for each gastric emptying study and mixed meal test that you complete. If you leave the study early, or we have to take you out of the study, you will be paid only for the tests you have completed.

It is important to know that payments for participation in a study are taxable income.

Will I have to pay for anything?
It will not cost you anything to be in the study.

You will still be responsible for your standard of care treatment whether you are participating in the GF-IGB System Treatment or the My New Weigh Meal Replacement Program.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled. If you leave this study, you will still receive your normal medical care.

Can I be removed from this study?
The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Sullivan immediately. Her phone number is 303-724-0017.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Shelby Sullivan. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Sullivan at 303-724-0017. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Sullivan with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

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.

Optional Permission for Future Contact
May we contact you for further undetermined studies conducted by Dr. Sullivan or Dr. Cornier? If yes, we will need to look at your Protected Health Information (PHI) to check for study eligibility

Yes_____ No_____

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.
The institutions involved in this study include

- University of Colorado Denver
- University of Colorado Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Shelby Sullivan, MD
12631 East 17th Ave Mail
Stop B158
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. [To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed].

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results, current medications and current or previous treatments you have undergone for obesity
- Research visits and research test records
- Psychological and mental health tests
- Blood samples and the data with the samples Billing or financial information

What happens to Data, Tissue, Blood and Specimens that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data, tissue, blood, or other specimens given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data, tissue, blood, or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

HIPAA Authorization for Optional Additional Study Procedures

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____I do not give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____