Informed Consent:

Gastric Artery Embolization Trial for Lessening Appetite Nonsurgically (GETLEAN)

NCT02248688

September 29th, 2014

INFORMED CONSENT

Revised 09/02/2014

TITLE:	Gastric Artery Embolization Trial for LEssening Appetite Nonsurgically (GET LEAN)
PROTOCOL NO.:	G140091 WIRB® Protocol #20141495
SPONSOR:	Dayton Interventional Radiology
INVESTIGATOR:	Mubin I. Syed, MD Suite 120 3075 Governor's Place Boulevard Kettering, Ohio 45409 United States
SITE(S):	Dayton Interventional Radiology Ste. 120 3075 Governors Place Blvd. Dayton, Ohio 45409 United States Ohio State University Medical Center 395 West 12th Avenue Columbus, Ohio 43210 United States
STUDY-RELATED PHONE NUMBER(S):	Mubin I. Syed, MD 937-424-2580 (24 hours)
SUB-INVESTIGATOR(S):	Kamal Morar, M.D 937-424-2580 Hooman Khabiri, M.D. 614-293-8315

PURPOSE

The purpose of this study is to collect safety and efficacy information on patients receiving left gastric artery embolization procedure. This is a pilot study. This study involves research. The purpose of the study is to determine if blocking the left gastric artery will result in significant weight loss. Left gastric artery embolization (blocking the left gastric artery) is experimental for weight loss. You will be expected to participate for 1 year.

You should be aware that it is possible that after having this procedure you will not be able to undergo standard weight loss procedures in the future because the blood supply to your stomach will have been altered, and surgical procedures on this part of the stomach may not be possible.

STUDY PROCEDURES
If you decide to participate you must be available to provide a bariatric history, physical examination, a blood draw for the appetite hormones of ghrelin, leptin, and cholecystokinin (CCK). You will also be required to perform a stool guiac test (a card you take home to test your stool). Some of the blood work required will be a complete blood count (CBC), blood chemistry (BUN/Creatinine), and clotting time (PT/PTT). Blood work will be needed at baseline (CBC, BUN/Creatinine, PT/PTT), 3 days (CBC, BUN/Creatinine), 1 week (CBC, BUN/Creatinine), and 1 month (CBC, BUN/Creatinine). You will also undergo a CT angiogram as a baseline study. You will also undergo upper endoscopy (at baseline and at 3 days after the embolization procedure), nuclear medicine gastric emptying study (at baseline and at 3 months after the embolization procedure). In addition, you will also be referred to a dietician and specialist in bariatric medicine that you will see over the course of the next year while you are enrolled in this study.

To assure that the procedure has not caused any complications, you must return for an upper endoscopy at 3 days. To confirm that the procedure is working well you must have a plasma ghrelin, leptin, and CCK level (blood test) performed 1 week, 1 month, 3 months, 6 months, and 12 months following the procedure. You will also be followed up at these times to check your weight, quality of life (quality of life survey form), and for any side effects. If you are diabetic you will be asked to obtain regular HgBA1C values and be followed closely by a diabetologist/endocrinologist who is experienced in taking care of patients who have undergone bariatric procedures). If any serious blood sugar issue arises (blood glucose <70 or >300), you and the accompanying responsible individual will also be instructed to contact your diabetologist or endocrinologist and also contact the physician who performed your procedure. If any other blood sugar issue arises, you and an accompanying responsible individual will be instructed to contact your diabetologist or endocrinologist and also contact the physician who performed your procedure. You will be informed that these instructions are to remain in effect throughout the entire study period (1 year). If you experience any side effects, you may be sent to the emergency room and/or admitted to the hospital to be evaluated by a gastroenterologist, bariatric surgeon, or general surgeon who may prescribe upper endoscopy or further radiological evaluation.

If you are a female of childbearing potential, you will be required to utilize 2 forms of contraception during the study (both oral contraception and barrier contraceptive methods). Please note that the initiation of the oral contraceptive method selected will be begun with sufficient lead time for the oral contraceptive to be effective, as that time varies among the drugs.

Left gastric artery embolization involves inserting a small tube, called a catheter, into the femoral artery at the top of the thigh or radial artery (in the wrist), either on the left or right side, and sliding the catheter through the aorta into the celiac artery (that supplies the upper abdomen). The left gastric artery (that supplies the fundus or upper stomach where the ghrelin producing cells are located) is blocked using small gel-like particles (BeadBlock) through the catheter and into the artery. You may experience pain in their upper abdomen afterwards that is usually temporary. You will receive local anesthetic such as lidocaine and/or intravenous sedation (Versed, Fentanyl, or Propofol). A closure device may be used to seal the artery puncture. You will need to lie on your back for 2 hours afterwards, if the closure device is successful or 4 to 6 hours if the closure device is unsuccessful. If the closure device did not work, manual compression will need to be applied to the puncture site in the groin or wrist.

BENEFITS
You may experience loss of weight over the next several months to years, however no guarantee of such changes can be offered. The research may increase our understanding of the role of gastric artery embolization in the treatment of obesity. On the other hand, your participation may not provide any additional useful medical information. You will be provided copies of published research arising from

this study.

RISKS
The risks of catheterization include allergy to the imaging dye, and bruising or bleeding or pain at the catheter insertion site. There is also a risk of catheter-related arterial injuries, including aneurysm formation, arterial dissection, and thrombosis which can result in hand/limb ischemia. Additional risks are kidney damage including contrast-induced acute renal injury and/or failure.

The risks of embolization (blocking the left gastric artery with BeadBlock particles) include death, stomach injury/pain, stomach ulceration/bleeding, stomach necrosis, loss of stomach function, irreversible damage to the stomach that could require surgery, heartburn, diarrhea, and exposure to radiation. Inadvertent embolization (blocking of an artery) to another organ (pancreas, liver, gallbladder, intestines, or spleen) may occur with possible resulting complications.

Further risks include potential end organ or limb ischemia/infarction, arterial injury, aspiration pneumonia, and /or abdominal bleeding. Another possibility is that you may lose more weight than you intended or is safe for you.

If any complications occur, hospitalization, emergency surgery or additional procedures may be necessary. This procedure has been used effectively for the emergency treatment of stomach bleeding for 40 years. The procedure may involve risks to the subject (or to the embryo or fetus, if the subject may become pregnant) which are currently unforeseeable.

You will not be enrolled in this study if you:

- Are less than 22 years of age
- Have had major surgery within the past eight weeks
- Have had previous gastric, pancreatic, hepatic and splenic surgery
- Have had previous radiation therapy to the left or right upper quadrant
- Have had any previous gastric, hepatic, or splenic embolization
- Have any history of portal venous hypertension
- Have a serum creatinine > 1.8 mg/dL (blood test to check your kidney function)
- Have a history of kidney problems
- Are pregnant or intend to become pregnant within one year
- Have a history of severe bleeding disorder or platelet count less than 40,000
- Have an allergy to materials in the embolic agents (acrylamido polyvinyl alcohol macromer)
- Are enrolled in another study
- Have a history of allergic reaction to iodinated contrast
- Have an abnormal baseline gastric emptying study
- Are taking anti-coagulants or antiplatelet drugs
- Are currently taking or requiring chronic use of NSAID or steroid medications
- Have any chronic upper gastrointestinal complaints such as pain, nausea or vomiting
- Have a history of peptic ulcer disease
- Have any indication of gastrointestinal bleeding as documented by positive stool guaiac and complete blood count with abnormalities.
- Have any contraindications for moderate sedation or general surgery
- Are enrolled in another study
- Are not willing, able, and mentally competent to provide written informed consent (to ensure that all study subjects demonstrate an understanding of the risks of the procedure and also participate in the informed consent).
- Have not failed previous attempts at weight loss through diet, exercise, and behavior modification (as it is recommended that conservative options, such as supervised low calorie diets combined

with behavior therapy and exercise, should be attempted prior to enrolling in this study).
Have any secondary causes of obesity such as Cushing's disease and hypothyroidism
Have an active substance abuse problem or alcoholism
Have defined noncompliance with previous medical care
Have certain psychiatric disorders such as schizophrenia, borderline personality disorder, and uncontrolled depression, and mental/cognitive impairment that limits the individual's ability to understand the proposed therapy.
Have mesenteric atherosclerotic disease or abdominal angina
Have a hiatal hernia
Have known aortic disease, such as dissection or aneurysm
Have a comorbidity such as cancer, peripheral arterial disease or other cardiovascular disease

STUDY COSTS
There will be facility and physician charges. Your health insurance may or may not cover these costs. If your health insurance does not cover the costs the study sponsors will only cover the costs of the embolization procedure, routine testing, and follow up related to the study. You may have costs that may result from your participation in the research study. You should talk with your insurance carrier before you make your decision because some insurance companies may not pay for costs associated with a research study.

COMPENSATION
You will not be paid for taking part in this study.

PARTICIPATION IS VOLUNTARY

a. Your participation in this study is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

b. There will be a process for early withdrawal. However, early withdrawal from the study may have a deleterious effect on your health as follow up testing will not be performed and early complications may not be recognized.

   The consequence of your decision to withdraw from the study is that you may face the additional costs of your follow up, including tests, if they choose to have them from another physician or facility.

c. The study investigators or the sponsor may discontinue your participation in the study at any time should you fail to meet any of the criteria of ongoing participation in the study. Circumstances may arise under which your participation may be terminated by the investigator. You may also be discontinued from the study, if it is in your best interest, or you do not consent to continue in the study after being told of changes in the research that may affect you. If you no longer meet inclusion criteria prior to the procedure you may be discontinued from the study. If new exclusion criteria arise during pre-procedure evaluation, you may be discontinued from the study. If you become pregnant, become incarcerated, institutionalized, become unavailable for follow up due to personal or extenuating circumstances, and/or develop an unrelated mental or physical illness that may cause uncontrollable weight gain/weight loss (examples heart failure, nephrotic syndrome, cancers, etc.) , you will be discontinued from the study. Should any of these circumstances arise, you would still be followed by the investigators for any potential complications related to the procedure, however you would be excluded from the study results.

d. New findings that may affect your willingness to continue participation will be provided to you.

ALTERNATIVE TREATMENTS

If you do not participate in this study, the following conventional procedures and treatments are available to you: You may continue your current treatment including diet, exercise and any other health care professional prescribed remedy, including bariatric surgery.

TREATMENT FOR POSSIBLE PHYSICAL INJURY RESULTING FROM RESEARCH PROCEDURES

a. I understand that in the event I suffer any physical injury as a result of my participation in this study, I should immediately contact the principal investigator (whose name is listed in the Miscellaneous section, later in this form), my primary treating physician, or a local Emergency Department, if the study investigator is unavailable.
b. I understand that medical treatment will not, necessarily, be provided free of charge.
c. Further information regarding the availability of medical treatment for injury suffered as a result of participating in this study may be obtained from the study sponsor by calling the Sponsor at 937-424-2580 (Dayton Interventional Radiology) or 614-293-8315(Ohio State University Department of Radiology).
d. I further understand that financial compensation for any physical injury I might suffer as a result of my participation in this study is not provided.

If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system.

CONFIDENTIALITY OF DATA

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.

A description of this clinical trial will be available on *http://www.clinicaltrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

This Consent Form explains how your personal health information will be used and who it will be given to ("disclosed") for this research study. It also describes your privacy rights, including your right to see your personal health information.

By signing the consent document for this study, you will give permission ("authorization") for the uses and disclosures of your personal health information that are described in this Consent Form. If you do not want to allow these uses, you should not participate in this study.

- The study doctor and staff will use your medical records and information created or collected during the study to conduct the study.
- The study data 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 the study data and may use your initials. Some study data may contain information that could be used (perhaps in combination with other information) to identify you (e.g., date of birth). If you have questions about the specific health information that will be provided, you should ask the study doctor.
- The study data may be used for research purposes to support the scientific objectives described in

the consent document and the process of getting regulatory approvals.

- Your study data maybe combined with data from other studies in research databases in order to study better 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 study data, either alone or combined with data from other studies, may be shared with regulatory authorities in the United States and other countries (including the U.S. Food and Drug Administration (FDA)), other institutions participating in the study, the Western Institutional Review Board® (WIRB®), and the ethical review board overseeing this study.
- Study data 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 ethical review board overseeing this study, and regulatory authorities in the United States and other countries (including the FDA). 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.
- Personal health information will not be disclosed to insurance companies unless required to do so by law, or unless you request it.
- Your medical records and study data may be held and processed on computers.
- Your personal health information may no longer be protected under the HIPAA privacy rule once it is disclosed by you or your study doctor.
- 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 study doctor. If you cancel your authorization, the study doctor and staff will no longer use or disclose your personal health information in connection with this study, unless the study doctor or staff needs to use or disclose some of your personal health information to preserve the scientific integrity of the study. Your study data that was collected before you canceled your authorization may still be used. If you cancel your authorization you will no longer be able to participate in the study. However, if you decide to cancel your authorization and withdraw from the study, you will not be penalized or lose any benefits to which you are otherwise entitled.
- Your authorization will expire December 31, 2064.

MISCELLANEOUS
This study involves research per 21 CFR 50.25(a)(1-8) and 21 CFR 50.25(b)(1-6).

A total of five subjects will be involved with this study.

If you have any questions about this study now or in the future, if at any time you feel you have had a research-related injury or a reaction to the study drug, or if you have questions, concerns, or complaints about the research, you may contact:

Principal Investigator
Mubin I. Syed, MD and Kamal Morar, MD
Dayton Interventional Radiology
3075 Governors Place Blvd., Ste 120
Dayton, OH 45409
phone: 937-424-2580
Hours Available: 24/7

or

Hooman Khabiri, MD,
Ohio State University Medical Center, Columbus, OH
303 Faculty Office Tower
395 W. 12th Ave
Columbus, OH 43210
phone: 614-293-8315
Hours Available: 24/7

If you have questions about your rights as a research subject or if you have questions, concerns, input or complaints regarding this study, you may contact:

Western Institutional Review Board
1019 39th Avenue SE, Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or (360) 252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

or

Ohio State University Biomedical IRB
Contact person: Karen N. Hale, RPh, MPH, CIP, Director
Office of Responsible Research Practices
300 Research Administration Building
1960 Kenny Road
Columbus, OH 43210
Tel: (614) 292-8613
Fax: (614) 688-0366

Sponsor:
Dayton Interventional Radiology
3075 Governors Place Blvd., Ste. 120
Dayton, OH 45409
phone: (937) 424-2580

and

Ohio State University Medical Center, Columbus, OH
303 Faculty Office Tower
395 W. 12th Ave
Columbus, OH 43210
phone: 614-293-8315

I acknowledge that I have fully read or have had read to me the contents of this consent form and the Experimental Subject's Bill of Rights, and that I understand both documents. I acknowledge that I have been given a signed and dated copy of this consent form as well as a copy of the Experimental Subject's rights.

I voluntarily consent to take part in this research study, and I understand that I may withdraw my consent at any time.

_____
Subject's Name (Printed)

_____ _____
Subject's Signature Date

_____
Person Conducting Consent (Printed)

_____ _____
Person Conducting Consent (Signature) Date