Study Protocol:

Gastric Artery Embolization Trial for Lessening Appetite Nonsurgically (GETLEAN)

NCT02248688

September 29th, 2014

Protocol Summary

- Purpose of research

The purpose of this research is to investigate a novel weight loss surgery that is easier than the classic bariatric surgeries by targeting the endocrine system.

- Background and hypothesis

Morbid obesity is a prevalent and deadly public health problem. Obesity affects about 30% of the United States population and accounts for a large portion of health expenditures. It is responsible for numerous comorbidities including diabetes mellitus and its complications, cardiovascular disease, sleep apnea, and premature osteoarthritis. It is seen both in young and old patients.

Left gastric artery embolization has been used for many decades as life saving treatment for upper gastrointestinal hemorrhage from the gastric fundus. Gastric artery embolization was first described by Rosch, et al. in 1972 who used autologous blood clot to embolize the right gastroepiploic artery. Bookstein, et al. in 1974 described a successful technique of left gastric artery embolization. Typically the common femoral artery is catheterized from the groin and the celiac artery is selected from the abdominal aorta followed by subselection of the left gastric artery. This artery is then embolized with gel foam, coils and/or particles.

We are intending to use BeadBlock to embolize the left gastric artery in the treatment of morbid obesity (BMI>35). Beadblock will be used intraarterially to occlude in this case the left gastric artery and its branches. The left gastric artery supplies the fundus of the stomach, where it is known that the hormone ghrelin (one of the hormones responsible for appetite) is produced. Ghrelin is a 28 amino acid hunger stimulating peptide and hormone that is produced mainly by P/D1 cells lining the fundus of the stomach and epsilon cells of the pancreas. Ghrelin has emerged as the first identified circulating hunger hormone. Ghrelin is also the only known circulating orexigen, or appetite enhancing hormone. By destroying the P/D1 cells in the fundus of the stomach, we are hoping to reduce ghrelin levels in the body, allowing the patient to feel less hungry than their baseline.

- Procedures

The patient's right groin is prepped and draped in a sterile fashion. 2% lidocaine was used to locally anesthetize the skin and soft tissues overlying the right common femoral artery. A 21-gauge micropuncture needle is utilized to attempt to puncture the right common femoral artery. A 0.018 inch guidewire is then advanced into the artery. A 5-French micropuncture sheath is advanced over the guidewire into the artery. A 5-French standard vascular sheath is then placed over a Bentson type guidewire.

A pigtail catheter is then utilized to perform an angiogram of the abdominal aorta at the level of the superior margin of T12. A power injection is then performed to determine the patency of the celiac and superior mesenteric arteries. The celiac artery would be selected utilizing a 4-French Simmons 1 catheter. A selective celiac angiogram is then performed in AP projection. This would allow visualization of the left gastric artery. A Simmons catheter over a Bentson guidewire is advanced into the left gastric artery. At this point, a gelfoam slurry is created by mixing the beads with half strength contrast. 10cc of the gelfoam slurry is injected into the left gastric artery and its branches until there is complete cessation of flow (stasis) within the left gastric artery and its branches. This is confirmed with followup contrast injection into the left gastric artery. The catheter is then withdrawn into the celiac arteries. A celiac arteriogram is then performed to confirm occlusion of the left gastric artery and its branches.

All catheters are removed and the insertion site is cleaned and wrapped in a sterile fashion.

After the general surgery, patients will undergo upper gastrointestinal endoscopy within 24 hours. Additionally, a second endoscopy will be performed within one week of the procedure to visualize the stomach lining.

- Risks

The major risks of this study are ischemic gastritis with ulcers and frank gastric necrosis. Additionally, rare non-target embolization can occur, but will be limited by live fluoroscopic imaging.

Risks also include being put under with general anesthesia. Rare risks include temporary mental confusion, lung infection, stroke, heart attack, and death. These complications are very rare and are most dependent on the patient's general health.

- Potential benefits

Typical bariatric surgery has multiple risks including gastrointestinal leaks, cholelithiasis, ventral incisional hernia, short bowel syndrome, dumping syndrome, and severe metabolic and nutritional derangements. The procedure we propose will be minimally invasive and target hormone-producing cells, instead of actually modifying the gastrointestinal tract significantly. If this procedure has been deemed successful, it will potentially be used as a safer alternative to the classic bariatric surgery. This will help the morbidly obese population with long-term weight loss.

- Inclusion and exclusion criteria

Volunteers must have met with a bariatric surgeon for a consult, and eligible for a bariatric surgery. Volunteers must be over the age of 18, and a BMI of greater than 35. However, patients cannot weigh more than 400 pounds, due to the operating table limit. Due to the use of contrast, patients must not have renal insufficiency, or a contrast allergy. Due to surgical restriction, patients must be able to lay flat in order to be operated on.