

Vertical Sleeve Gastrectomy and Lifestyle Modification for the Treatment of Non-Alcoholic Steatohepatitis

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. ages 30 to 70 years 2. diagnosed with NASH with a total NAS ≥ 4 including a ballooning score of at least 1, or diagnosed with T2DM or prediabetes, HbA1c $< 9\%$ Body Mass Index (BMI): 35.0-50.0 kg/m² 3. willing to accept either surgery or life style changes 4. must have insurance with no exclusion for obesity related treatments or management of obesity surgery complications. applies to all participants enrolled in the study 5. evidence of liver fat present in the baseline MR images 6. suitable for liver biopsy

Exclusion Criteria:

1. cardiovascular event (myocardial infarction, acute coronary syndrome, coronary artery angioplasty or bypass, stroke) in the past six months 2. pulmonary embolus or thrombophlebitis in the past six months 3. cancer diagnosis unless disease free for five years 4. alcohol intake more than one drink per day 5. other physical or mental health disease (study staff will review)

Conditions & Interventions

Interventions:

Behavioral: Lifestyle Modification Counseling, Procedure: Vertical Sleeve Gastrectomy

Conditions:

Digestive & Liver Health

Keywords:

Bariatric Surgery, NASH, VSG, Clinics and Surgery Center (CSC), fatty liver, gastrectomy, sleeve, sleeve gastrectomy, weight loss

More Information

Description: This study is comparing the treatment of Non-Alcoholic Steatohepatitis (NASH) with either lifestyle changes or obesity surgery with lifestyle changes. Participants must be 30-70 years old, have a BMI of 35.0-60.0 kg/m², have health insurance that will pay for obesity surgery, and be willing to accept either treatment.

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Phase: N/A

IRB

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