

Randomized Double Blinded Placebo-Controlled w/Semaglutide to Prevent Weight Gain After Liver Transplant

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 75 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Male or female age 18-75 years who received LT for any indication (i.e. NASH, hepatitis C, alcohol-induced cirrhosis, autoimmune hepatitis, etc.) * Liver transplant surgery within 8-24 weeks prior to randomization * Fasting glucose ≥ 125 mg/dL or presence of diabetes (HbA1c $\geq 6.5\%$ or use of diabetes medications) or pre-diabetes (HbA1c $\geq 5.7\%$) * Ability to provide informed consent * Discharged from the hospital following LT surgery * Tolerating diet * Normal graft function (determined by treating hepatologist/surgeon based on clinical status and hepatic panel) * Stable immunosuppression according to the VCU (Virginia Commonwealth University) post-LT protocols (i.e. calcineurin inhibitors + mycophenolate) * Eligible female patients will be (1) non-pregnant, evidenced by a negative urine pregnancy test, (2) non-lactating, (3) surgically sterile or post-menopausal, or they will agree to continue to use an accepted method of birth control during the study

Exclusion Criteria:

* BMI ≤ 27 kg/m² * GFR (Glomerular Filtration Rate) ≤ 25 ml/min/1.73m² * Type 1 autoimmune diabetes (by anti-GAD (glutamic acid decarboxylase) or history of ketoacidosis) * History of gastroparesis * Familial or personal history of medullary thyroid cancer or MEN (Multiple Endocrine Neoplasia) 2 * History of pancreatitis * History of active malignancy post-LT with the exception of non-melanoma skin cancers * History of uncontrolled or unstable diabetic retinopathy or maculopathy * Acute cellular rejection * Hepatic artery thrombosis * Medical non-compliance * Active treatment with GLP (glucagon-like peptide)-1RA (receptor agonist) or SGLT (sodium-glucose cotransporter)-2 inhibitors at time of screening * History of hypersensitivity to semaglutide or its excipients * Women who are nursing, pregnant, or planning to become pregnant during the study, or are not using adequate contraceptive measures

Conditions & Interventions

Interventions:

DRUG: Semaglutide Pen Injector, DRUG: Placebo

Conditions:

NAFLD

Keywords:

Liver Transplant

More Information

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Principal Investigator:

Phase: PHASE2

IRB

Number:

System ID: NCT05424003

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