Efficacy, Safety, and Pharmacokinetics of Tirzepatide Once Weekly versus Placebo in Adolescent Participants Who have Obesity, or are Overweight with Weight-Related Comorbidities: A Randomized, Double-Blind Trial

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Up to 18 years old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 12 to 17 years old - have obesity, as defined by BMI equal to or above the 95th percentile for age and sex, on age- and sex-specific growth chart - OR be overweight, as defined by BMI equal to or above the 85th percentile but less than the 95th percentile for age and sex, on age- and sex-specific growth chart, with at least 1 weight-related comorbidity. These include: dyslipidemia, pre-hypertension, hypertension, nonalcoholic fatty liver disease, obstructive sleep apnea, prediabetes, or Type 2 Diabetes - those with Type 2 Diabetes have been treated with either diet and exercise alone or stable treatment with metformin for at least 90 days prior to screening and have a HbA1c<9.0% Type 2 Diabetes

Exclusion Criteria:

- decrease in body weight more than 5 kilogram (kg) (11 lbs.) within 90 days - have Type 1 Diabetes - have taken within 90 days before screening or intend to start prescribed or over-the-counter medications, or alternative remedies including herbal or nutritional supplements, intended to promote body weight reduction - have or plan have a weight reduction surgical procedure - additional exclusion criteria apply (study staff will review)

Conditions & Interventions

Interventions:
Drug: Placebo, Drug: Tirzepatide
Conditions:
Children's Health, Diabetes & Endocrine
Keywords:
BMI, Obesity, Overweight, T2D, Type 2 Diabetes

More Information

Description: This study is being done to see how safe an investigational drug is and how well it will work to help people with obesity, or overweight with weight-related conditions like hypertension, dyslipidemia, obstructive sleep apnea, non-alcoholic fatty liver disease, or diabetes. If you qualify to be in the study, you will be given frequent lifestyle and behavioral counseling for the first 12 weeks of the study. The counseling will consist of advice on physical activities and dietary advice on healthy eating. During the treatment period, you will receive either tirzepatide or placebo. Placebo is a solution that looks like the study drug but has no medicine. The chance that you will get the study drug is 2 in 3. This phase will last about 72 weeks.
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