Efficacy, Safety, and Pharmacokinetics of Tirzepatide (LY3298176) Once Weekly Versus Placebo in Pediatric Participants 6 to Less Than 12 Years of Age Who Have Obesity (ADVANCE-SURMOUNT-KIDS)

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 6 years to 11 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

J4M-MC-PW02

- Are 6 to less than 12 years of age (Tanner stage 1 to 5 inclusive)
- Have:
    - a body weight of ≥ 40 kilograms (kg) (88 pounds), and
    - been diagnosed with obesity, as defined by BMI equal to or above the 95th percentile for age and sex, on age- and sex-specific growth chart

J4M-MC-PWMP

- Have a history of at least 1 unsuccessful effort to lose sufficient body weight after participation in a structured lifestyle modification program (diet and exercise counseling for at least 3 months) prior to screening.
- Obesity as defined by BMI equal to or above the 95th percentile for age and sex (on age- and gender-specific growth chart [CDC-NCHS, 2022])

Exclusion Criteria:

J4M-MC-PW02

- Have a history of
    - proliferative diabetic retinopathy
    - diabetic macular edema, or
    - nonproliferative diabetic retinopathy that requires acute treatment

J4M-MC-PWMP

- Have undergone or plan to undergo weight reduction procedure during the study, such as, but not limited to:
    - gastric bypass
    - sleeve gastrectomy
    - restrictive bariatric surgery, such as Lap-Band® gastric banding, or
    - any other procedure intended to result in weight reduction.
- Have a diagnosis that is a secondary cause of obesity or have a history of abrupt onset of obesity suggesting a secondary cause, such as hypothalamic, monogenetic, syndromic, or endocrine causes.
- Have type 1 diabetes or history of ketoacidosis, or hyperosmolar state.
- Have HbA1c >9.0% (75 mmol/mol) as measured by central laboratory at screening.
- Have a family or personal history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia Syndrome Type 2.

Conditions & Interventions

Interventions:
DRUG: Tirzepatide, DRUG: Placebo
Conditions:
Obesity
Keywords:
Pediatric, Children

More Information

Description:
The main purpose of this study, performed under Master Protocol J4M-MC-PWMP (NCT06672549), is to evaluate the efficacy, safety, and pharmacokinetics of tirzepatide as an addition to healthy lifestyle in participants 6 to less than 12 years of age, with obesity. Participation in the study will last about 104 weeks. Participants who have completed the primary 104-week PW02 study (including the 4-week safety follow-up period), will have the opportunity to receive an additional 156 weeks of treatment with tirzepatide as well as continuing the lifestyle intervention.

Contact(s): Trial questions or participation questions: 1-877-CTLILLY (1-877-285-4559) or - LillyTrials@Lilly.com
Phase: PHASE3
System ID: NCT07817875

Thank you for choosing StudyFinder. Please visit http://studyfinder.cchmc.org to find a Study which is right for you and contact clinicalstudies@cchmc.org if you have questions or need assistance.