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Background: Metabolic and bariatric surgery (MBS) is currently the most effective weight loss treatment in adults and children with severe obesity. However, up to 50% of adolescents continue to have obesity three years post-MBS. Vertical sleeve gastrectomy (VSG), the most common MBS performed in adolescents, causes an increase in post-prandial glucagon-like peptide 1 (GLP-1) post-operatively, but the duration of this incretin hormone response is unclear. Liraglutide, a GLP-1 analogue, may supplement the physiological increase in GLP-1 following VSG and promote weight loss via appetite suppression. We hypothesized that daily liraglutide treatment would significantly reduce body weight in adolescents who had previously undergone VSG but who continued to have insufficient weight loss. This abstract reports interim data from our prospective clinical trial of liraglutide in adolescents with obesity after VSG (ClinicalTrials.gov Identifier: NCT04883346). Methods: This trial is an active, open-label, phase II pilot study to investigate the efficacy of daily subcutaneous liraglutide to promote reduction of BMI in adolescents with persistent obesity 1 year or more after VSG. The primary objective is to determine the effect size for the change in BMI of liraglutide 3.0 mg daily at 16 weeks in study participants to calculate the sample size of a subsequent randomized controlled trial. Inclusion criteria are age 12 to 20.99 years, good general health, BMI≥30 kg/m2, and a personal history of VSG \geq 1-year prior. Exclusion criteria include major medical illnesses, use of medications associated with weight gain, or use of weight-loss medications within the last 3 months of screening. Liraglutide is initiated at 0.6 mg daily and escalated by 0.6mg weekly to 3 mg/d for the last 12 weeks of treatment. Participants receive monthly nutrition counseling throughout the study. Results: At time of interim analysis (3/24/22), 26 participants (baseline age 18±1.9y, mean±SD; 65% female; 55% black; baseline BMI 42. 0±7. 0 kg/m2) were screened and 20 started liraglutide. Among 17 participants who reached 8 weeks of treatment, mean absolute change in weight was -3.9±2.6 kg, percent change in weight was -3.6±2.6%, absolute change in BMI was -1.4±0.9 kg/m2, and percent change in BMI was -3.6±2.6%. There were no serious treatment-emergent adverse events (TEAEs) reported; 16/20 participants reported non-serious TEAEs including low energy (40%), nausea (40%), and vomiting (20%). In this interim analysis of an open-label phase II pilot study, the mean weight change from baseline was -3.6% after 8 weeks of liraglutide treatment in adolescents with persistent obesity after VSG. No new TEAEs were identified. Completion of this study will help determine if weight reduction with liraglutide suggests value to carry out a randomized placebo controlled study using liraglutide.

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Phase II Open-label Pilot Trial Of Liraglutide In Adolescents With Obesity After Vertical Sleeve Gastrectomy: Interim Results From 8-weeks Of Treatment

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