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Title:	**Liraglutide** in an Adolescent Population with Obesity: A Randomized, Double-Blind, Placebo-Controlled 5-Week Trial to Assess Safety, Tolerability, and **Pharmacokinetics** of **Liraglutide** in Adolescents Aged 12-17 Years.
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Humans
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Hypoglycemia / ep [Epidemiology]
Injections, Subcutaneous
Liraglutide / ae [Adverse Effects]
*Liraglutide / pk [Pharmacokinetics]
*Liraglutide / tu [Therapeutic Use]
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Patient Safety
Pediatric Obesity / di [Diagnosis]
*Pediatric Obesity / dt [Drug Therapy]
Reference Values
Risk Assessment
Treatment Outcome

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Abstract:

OBJECTIVES: To investigate the safety, tolerability, and pharmacokinetics of liraglutide in adolescents with obesity.

STUDY DESIGN: This was a randomized, double-blind, placebo-controlled trial. Twenty-one subjects, aged 12-17 years and Tanner stage 2-5, with obesity (body mass index [BMI] corresponding to both a BMI >=95th percentile for age and sex and to a BMI of >=30 kg/m^2 for adults; additionally, BMI was <=45 kg/m^2) were randomized (2:1) to receive 5 weeks of treatment with liraglutide (0.6 mg with weekly dose increase to a maximum of 3.0 mg for the last week) (n = 14) or placebo (n = 7). The primary endpoint was number of treatment-emergent adverse events (TEAEs). Secondary endpoints included safety measures, and pharmacokinetic and pharmacodynamic endpoints.

RESULTS: All participants receiving liraglutide, and 4 receiving placebo (57.1%), had at least 1 TEAE. The most common TEAEs were gastrointestinal disorders. No severe TEAEs, TEAE-related withdrawals, or deaths occurred. Twelve hypoglycemic episodes occurred in 8 participants receiving liraglutide and 2 in 1 participant receiving placebo. No severe hypoglycemic episodes were reported. Liraglutide exposure in terms of trough concentration increased with dose, although dose proportionality was confounded by unexpectedly low trough concentration values at the 2.4 mg dose. Exposure in terms of model-derived area under the plasma concentration time curve from 0 to 24 hours after dose in steady state was similar to that in adults with obesity.

CONCLUSIONS: Liraglutide had a similar safety and tolerability profile compared with adults when administered to adolescents with obesity, with no unexpected safety/tolerability issues. Results suggest that the dosing regimen approved for weight management in adults may be appropriate for use in adolescents.

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