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Abstract: **BACKGROUND:** Childhood obesity is a major public health concern with limited treatment options.

OBJECTIVE: The aim of this study was to assess safety, tolerability, pharmacokinetics, and pharmacodynamics during short-term treatment with liraglutide in children (7-11 y) with obesity.

METHODS: In this randomized, double-blind, placebo-controlled trial, 24 children received at least one dose of once-daily subcutaneous liraglutide (n = 16) or placebo (n = 8) starting at 0.3 mg with weekly dose escalations up to 3.0 mg or maximum tolerated dose, and 20 children completed the trial (14 in the liraglutide group and six in the placebo group). The primary endpoint was the number of adverse events.

RESULTS: Baseline characteristics (mean +/- standard deviation) included the following: age 9.9 +/- 1.1 years, weight 71.5 +/- 15.4 kg, and 62.5% male. Thirty-seven adverse events were reported in nine liraglutide-treated participants (56.3%) versus 12 events in five placebo-treated participants (62.5%). Most adverse events were mild in severity, three were of moderate severity, and none were severe. Gastrointestinal disorders were the most frequently reported events occurring in 37.5% of liraglutide-treated participants compared with placebo (12.5%). Six asymptomatic hypoglycaemic episodes occurred in five participants of whom four were liraglutide treated. Liraglutide exposure was consistent with dose proportionality. Body weight was the only covariate to significantly impact exposure. A significant reduction in body mass index (BMI) Z score from baseline to end of treatment (estimated treatment difference: -0.28; P = 0.0062) was observed.

CONCLUSION: Short-term treatment with liraglutide in children with obesity revealed a safety and tolerability profile similar to trials in adults and adolescents with obesity, with no new safety issues.

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