

gestation. Of the 24 subjects who were >6 months post-intervention, 10 were pregnant and had completed 28 weeks gestation.

Results: Weight loss in the MWL ($n=28$) and SWL ($n=34$) groups was 2.1% and 13.1% respectively. Mean reduction in plasma glucose after 12 weeks was 1.24% (SE 1.40) in MWL and 9.12% (SE 1.83) in SWL group. Of those who achieved pregnancy (MWL=3, SWL=7), mean decrease in plasma glucose between the start of the weight loss program and 26–28 week gestation was 1.85% (SE 1.83) and 11.51% (SE 3.17) in the MWL and SWL groups respectively.

Conclusion: This pilot data suggests that, in obese women, pre-conception weight loss results in a decrease in fasting plasma glucose which is maintained into pregnancy. The reduction in plasma glucose is greater when substantial pre-pregnancy weight loss is achieved.

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265

Liraglutide 3.0 mg in obese/overweight adults with or without prediabetes with baseline BMI <35 vs ≥ 35 kg/m² in the SCALE Obesity and Prediabetes 56-week randomized, double-blind, placebo-controlled trial



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Background: SCALE Obesity and Prediabetes (NCT01272219) randomized 3731 subjects (mean age 45 years, male 22%, mean BMI 38 kg/m², 61% with prediabetes) 2:1 to liraglutide 3.0 mg or placebo (PBO) as adjunct to diet and exercise (D&E) for 56 weeks.

Methods: This post-hoc analysis compared efficacy and safety results for subjects with BMI < vs ≥ 35 kg/m² at baseline. The treatment effect of liraglutide across baseline BMI subgroups was evaluated by statistical testing of interaction between treatment and baseline BMI subgroup.

Results: Baseline characteristics were similar between liraglutide and PBO subgroups (BMI < vs ≥ 35 kg/m²) except for body weight (90.1 and 89.9 kg; 115.1 and 115.0 kg) and prevalence of prediabetes (54.0 and 51.1%; 65.3 and 66.1%); both were higher with BMI ≥ 35 kg/m². At 56 weeks, greater mean and categorical weight loss were seen with liraglutide vs PBO in both subgroups (mean: -8.2 and -7.9%; -2.7 and -2.6%) as well as greater improvements in systolic BP, FPG, and IWQoL-Lite total score. These treatment effects of liraglutide were all independent of baseline BMI (< vs ≥ 35 kg/m²; $p > 0.05$), except for the IWQoL-Lite physical function sub-score, which improved more with BMI ≥ 35 kg/m² ($p = 0.04$).

Adverse events (AEs) and serious AEs were generally comparable across BMI subgroups. In both liraglutide subgroups (BMI < or ≥ 35 kg/m²), more subjects reported nausea (40 vs 40%) than PBO (15 vs 15%). Gallbladder disorders were similar in liraglutide subgroups (18 [2.1%] vs 37 [2.3%] subjects) but higher than PBO (3 [0.7%] vs 7 [0.9%] subjects). Similar results were seen for adjudicated events of acute pancreatitis (liraglutide: 2 [0.2%] vs 5 [0.3%] subjects; PBO: 0 vs 1 [0.1%] subject).

Conclusions: The effects of liraglutide 3.0 mg, as adjunct to D&E, on body weight, metabolic control and safety were similar in subjects with baseline BMI < and ≥ 35 kg/m².

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