



Synopsis of the original article
‘Effect of Subcutaneous Semaglutide vs Placebo as an Adjunct to Intensive Behavioral Therapy on Body Weight in Adults with Overweight or Obesity: The STEP 3 Randomized Clinical Trial’

Wadden TA, et al. JAMA. 2021 Feb 24;e211831

Synopsis created and reviewed by Novo Nordisk

Introduction



Weight loss improves cardiometabolic risk factors in people with overweight or obesity



The most effective noninvasive approaches for weight loss include intensive lifestyle intervention and pharmacotherapy



Semaglutide is a once-weekly treatment that is being evaluated for weight management in people with overweight or obesity

Trial design: Phase 3a, randomized, double-blind, parallel-group study



Study objective

To compare the effects of once-weekly SC semaglutide 2.4 mg versus placebo for weight management, as adjunct to intensive behavioral therapy with initial low-calorie diet, in adults with overweight or obesity



Adults with BMI ≥ 30 kg/m² (or ≥ 27 kg/m² plus ≥ 1 weight-related comorbidity)



No history of diabetes

R

2:1

Semaglutide
2.4 mg SC once-weekly

Both in combination with low-calorie diet for the first 8 weeks + intensive behavioral therapy for 68 weeks

Placebo
SC once-weekly



Coprimary endpoints

- Percentage change in body weight at week 68
- Proportions of participants with $\geq 5\%$ weight reduction at week 68



Safety endpoint

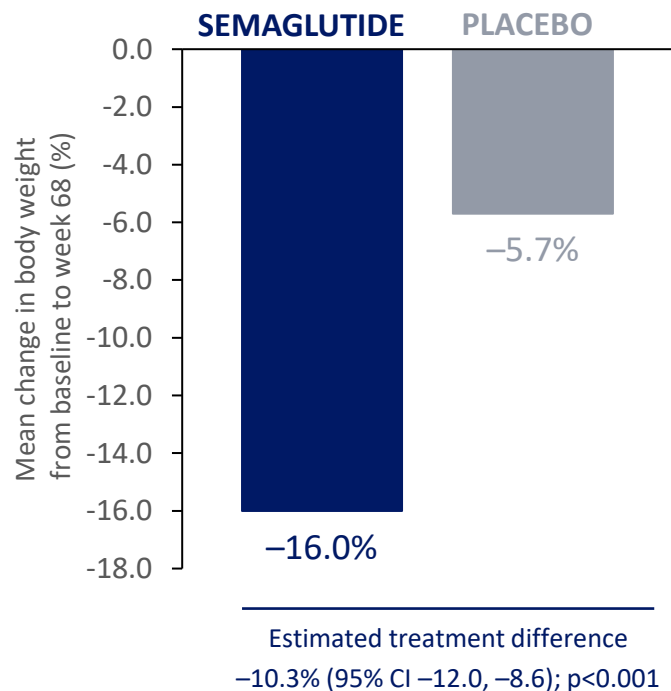
- Adverse events

Intensive behavioral therapy involved 30 counselling sessions
BMI, body-mass index; R, randomized; SC, subcutaneous

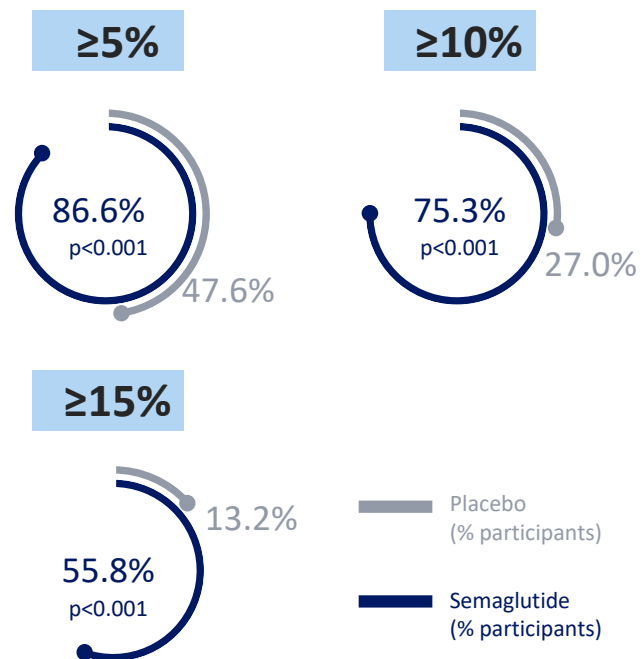
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Semaglutide once weekly led to greater weight loss than placebo when combined with intensive lifestyle intervention

Mean change in body weight (%) from baseline to week 68*



Proportions of participants achieving weight loss of $\geq 5\%$, $\geq 10\%$ and $\geq 15\%$ at week 68



Safety data

Gastrointestinal AEs were more frequent with semaglutide (82.8%) versus placebo (63.2%)

Treatment discontinuations owing to gastrointestinal AEs were more frequent with semaglutide compared to placebo (3.4% versus 0%)

*Treatment policy estimand. AE, adverse event; CI, confidence interval

Conclusions



Among adults with overweight or obesity, once-weekly **semaglutide 2.4 mg** combined with intensive behavioral therapy and an initial low-calorie diet, produced significantly greater weight loss over 68 weeks than the same behavioral and dietary intervention with placebo