STEP 1
WEIGHT MANAGEMENT

Wegovy™ (semaglutide) injection versus Placebo

⊕ Hover over the plus icon to view additional details.

STEP 1 was a **68-week**, phase 3, randomized, **placebo-controlled**, double-blind, multi-center trial in **1961 adult patients** with obesity or overweight and at least 1 weight-related comorbidity.[1,a]

Select Eligibility Criteria[1]

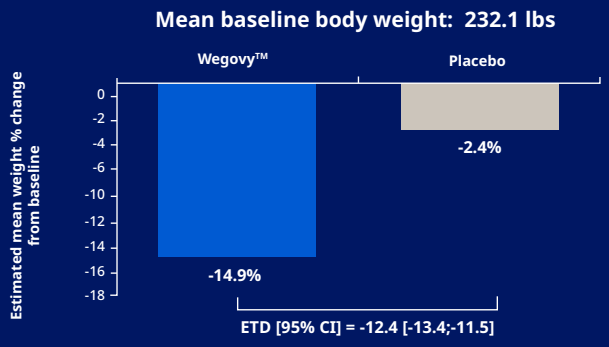
- BMI: ≥30 kg/m², or ≥27 kg/m² with at least 1 weight-related comorbidity[a]
- Baseline glycosylated hemoglobin (A1C) <6.5%
- Stable body weight for at least 90 days

Study Design[1]

Patients were randomized (**2:1**) to blinded treatment with either **Wegovy™** or **placebo**, each once weekly. ⊕

Key Results at 68 Weeks[1]
Treatment policy estimand[b]

Coprimary efficacy endpoint: Mean body weight % change from baseline to Week 68



Analysis at Week 68	ETD	95% CI	*P*-value
Wegovy™ vs placebo	-12.4	[-13.4;-11.5]	<.001

Coprimary efficacy endpoint: Achievement of ≥5% weight loss at Week 68

Wegovy™ vs placebo	OR	95% CI	*P*-value
≥5%	11.2	[8.9;14.2]	<.001

Proportion of patients with a body weight reduction ≥5% at Week 68 (observed values)

86.4% of patients on Wegovy™

31.5% of patients on placebo

Other confirmatory secondary endpoints:

- **WEIGHT LOSS OF ≥10% AND ≥15%**
- **WAIST CIRCUMFERENCE**
- **SYSTOLIC BLOOD PRESSURE**
- **SF-36 PHYSICAL FUNCTIONING SCORE**
- **IWQOL-LITE-CT PHYSICAL FUNCTION SCORE**

Safety[1]

- The most common adverse events (AEs) were gastrointestinal in nature, including nausea, diarrhea, and vomiting. ⊕
- More patients treated with Wegovy™ discontinued treatment due to AEs than those treated with placebo (7.0% vs 3.1%, respectively), primarily due to gastrointestinal AEs (4.5% vs 0.8%, respectively).
- Serious AEs were reported in 9.8% of patients treated with Wegovy™ and 6.4% of patients treated with placebo.

[a]Weight-related comorbidities include hypertension, dyslipidemia, obstructive sleep apnea and cardiovascular disease.
[b]The treatment policy estimand assessed effect regardless of rescue treatment or treatment discontinuation.
A1C: glycosylated hemoglobin; AE: adverse event; BMI: body mass index; CI: confidence interval; ETD: estimated treatment difference; IWQoL-Lite-CT: Impact of Weight on Quality of Life-Lite Clinical Trials Version; lbs: pounds; OR: odds ratio; SF-36: Short Form 36.
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Reference: 1. Wilding JPH, Batterham RL, Calanna S, et al. Once-Weekly Semaglutide in Adults with Overweight or Obesity. *N Engl J Med*. 2021;384(11):989.