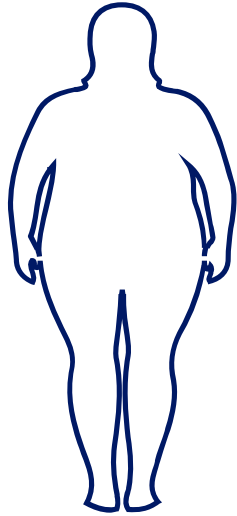


Synopsis of the original article
‘Semaglutide 2.4 mg for the treatment of obesity: Key elements of the STEP trials 1 to 5’

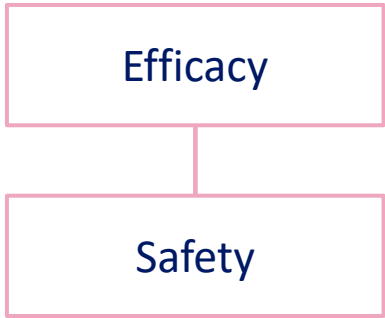
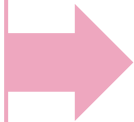
Kushner RF, et al. Obesity (Silver Spring). 2020;28(6):1050-1061
Synopsis created and reviewed by Novo Nordisk

Introduction



The obesity epidemic is a public health concern, warranting further research into pharmacological treatments for weight management as an adjunct to lifestyle interventions

The Semaglutide Treatment Effect in People with obesity (STEP) program aims to investigate the effect of semaglutide vs placebo in adults with obesity or overweight on:



Methods: STEP program includes five phase 3 clinical trials



The primary endpoint for STEP 1–5 trials is **weight loss**



STEP is the phase 3a/3b clinical development programme for subcutaneous semaglutide 2.4 mg weekly for weight management

STEP 1–4
Phase 3a

Semaglutide 2.4 mg

68 weeks + 7 week follow-up

The treatment period in all STEP trials is followed by a 7-week period off treatment to account for the long half-life of semaglutide

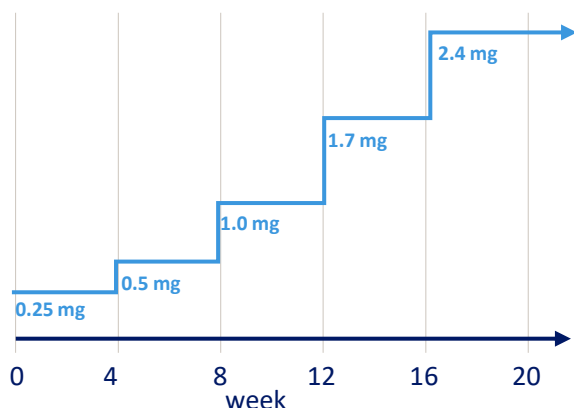
STEP 5
Phase 3b

Semaglutide 2.4 mg

104 weeks + 7 week follow-up

Dose escalation

Semaglutide 2.4 mg once weekly treatment is initiated at 0.25 mg, followed by increments every 4 weeks to 0.5, 1.0, 1.7, and 2.4 mg once weekly



Across the STEP programme



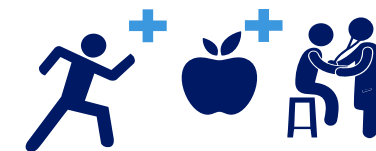
Treatment with semaglutide 2.4 mg once weekly will be compared to placebo, as an adjunct to lifestyle intervention

STEP 2



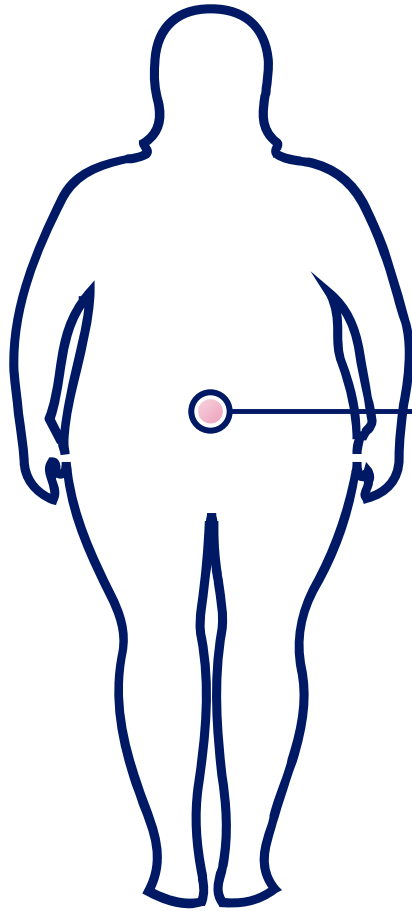
In STEP 2 only, people with type 2 diabetes were included

STEP 3

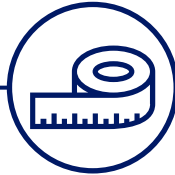


In STEP 3 only, lifestyle intervention comprises intensive behavioral therapy, an initial 8-week low-energy diet and higher target for physical activity

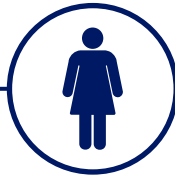
Results: Participants' characteristics



Mean age: 46.2–55.3 years



Mean waist circumference: 113.0–115.7 cm



Mostly female (mean: 74.1–81.0%)

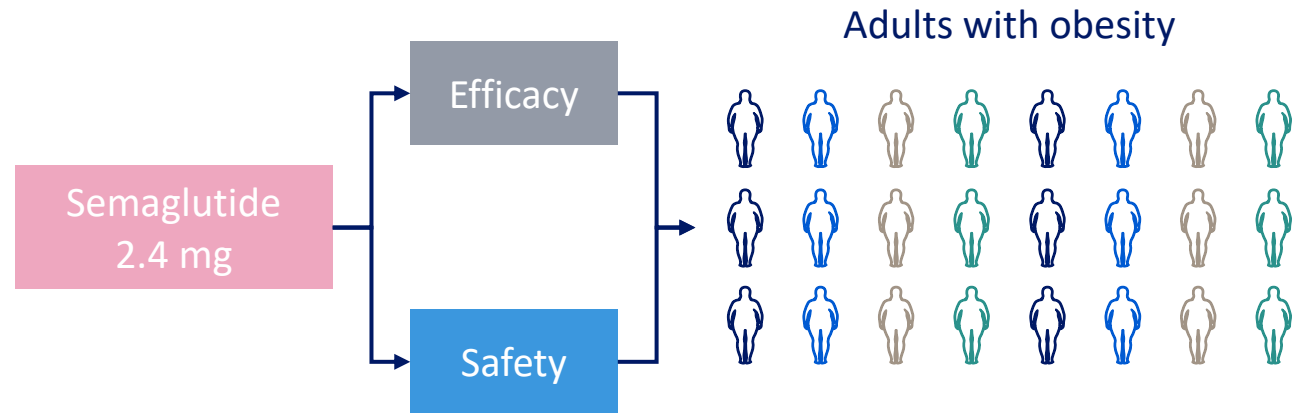


Mean BMI: 35.7–38.5 kg/m²

Conclusions



The STEP phase 3 trial program evaluates the efficacy and safety of semaglutide 2.4 mg subcutaneously once weekly in a broad population



The program will provide insights on WM in people with obesity with and without type 2 diabetes and on long-term follow-up