Full Title: Effect and Safety of Semaglutide 2.4 mg Once-Weekly in Subjects with Overweight or Obesity

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Study Objectives:
To compare the safety and tolerability of semaglutide s.c. 2.4 mg once-weekly versus semaglutide placebo as an adjunct to a reduced-calorie diet and increased physical activity in subjects with overweight or obesity on:

- Body weight
- Cardiovascular risk factors
- Clinical outcome assessments

To quantify the average treatment effect of semaglutide relative to semaglutide placebo after 68 weeks, as an adjunct to a reduced-calorie diet and increased physical activity, in all randomized subjects regardless of adherence to treatment and regardless of starting rescue interventions (weight management drugs or bariatric surgery).

Inclusion Criteria:
- Male or female 18 years or older at the time of consent
- Subjects enrolled into protocol with a body mass index (BMI) ≥30.0 kg/m² at the screening visit
- Subjects with at least one unsuccessful weight loss attempt

Exclusion Criteria:
- Subjects screened or diagnosed with type 1 or type 2 diabetes, hypothyroidism/hyperthyroidism, obesity induced by endocrine disorders (e.g. Cushing syndrome), severe psychiatric disorders (e.g. schizophrenia, bipolar disorder), or history of a suicidal attempt
- Subjects treated with glucose lowering agent(s) within 90 days before screening
- Subjects with a personal family history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome type 2
- Subjects with a history of pancreatitis (acute or chronic)
- Subjects with previous surgical treatment for obesity less than one year prior to screening (e.g. liposuction, abdominoplasty)
• Subjects with a history of major depressive disorder within two years of randomization

**Affiliations & Sponsors**
Novo Nordisk

**Status**
Closed to Enrollment

**Keywords**
overweight, obesity, weight-loss