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Synopsis of the original article

Efficacy and safety of once-weekly semaglutide 2.4 mg in people with obesity and prediabetes (STEP 10): A randomised, double-blind, placebo-controlled, multi-centre phase 3 trial

McGowan B et al. *Lancet Diabetes Endocrinol* 2024;
https://doi.org/10.1016/S2213-8587(24)00182-7

Synopsis created and reviewed by Novo Nordisk

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Introduction

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The aim of STEP 10 was to evaluate the efficacy and safety of once-weekly subcutaneous semaglutide 2.4 mg versus placebo as an adjunct to lifestyle intervention in participants with obesity and prediabetes at baseline, with change in body weight and reversion to normoglycaemia assessed as primary endpoints

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STEP 10 trial design

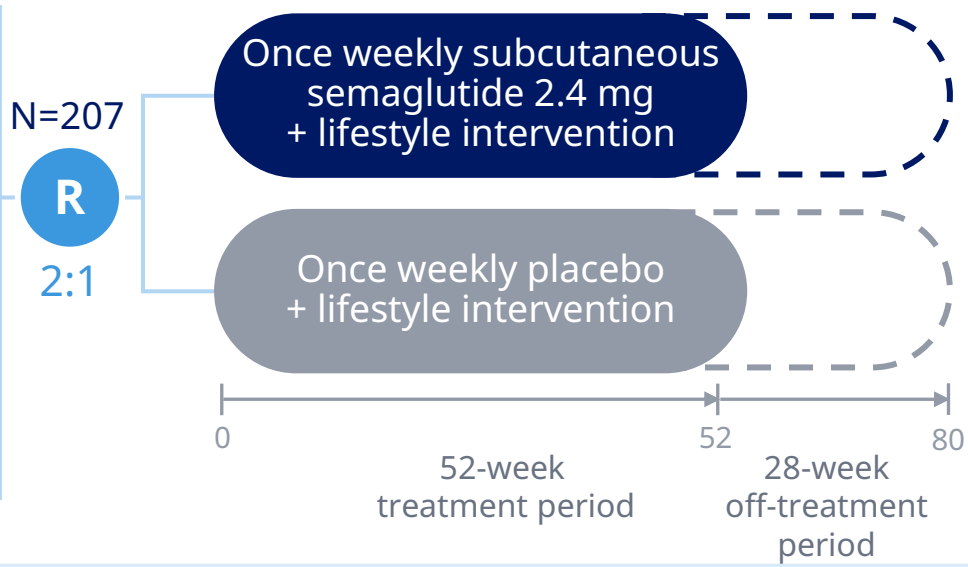
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Trial design

Randomised, double-blind, parallel-group, multicentre, phase 3 trial of once-weekly subcutaneous semaglutide 2.4 mg versus placebo plus lifestyle intervention

Adults with obesity and prediabetes (according to NICE criteria)

History of diabetes



Primary endpoints

Percentage change in body weight and proportion of participants reverting to normoglycaemia (HbA_{1c} <6.0% [<42 mmol/mol] and FPG <5.5 mmol/L) at week 52

Selected safety outcomes

Assessed in all participants who received at least one dose of study drug

FPG, fasting plasma glucose; HbA_{1c}, glycated haemoglobin; NICE, National Institute for Health and Care Excellence; R, randomisation.

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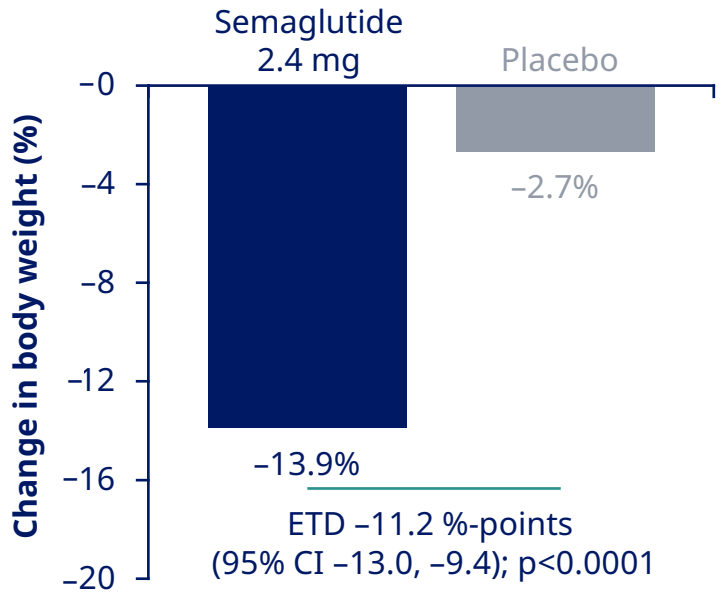
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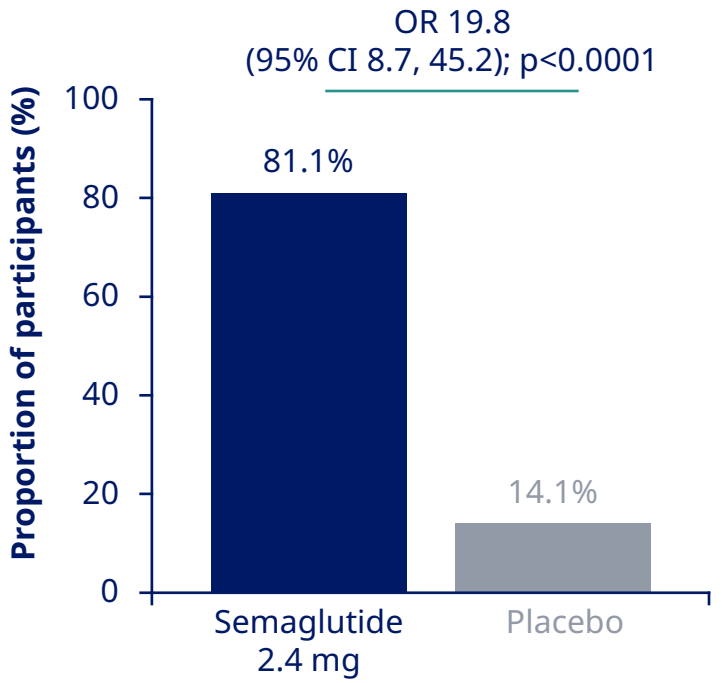
Semaglutide 2.4 mg provided superior reduction in body weight and increased reversion to normoglycaemia versus placebo

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Change in body weight from baseline to week 52



Proportion of participants achieving normoglycaemia at week 52



Safety

Serious adverse events

8.7% of participants with semaglutide 2.4 mg versus **8.7%** with placebo

Adverse events leading to treatment discontinuation

5.8% of participants with semaglutide 2.4 mg versus **1.4%** with placebo

CI, confidence interval; ETD, estimated treatment difference; OR, odds ratio.

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Conclusions



The results of STEP 10 support **semaglutide 2.4 mg** as an efficacious treatment option for **weight management** and highlight the **glycaemic benefit** of semaglutide 2.4 mg treatment in participants with **obesity** and **prediabetes**

The **safety and tolerability profile** of semaglutide 2.4 mg was **consistent** with previous studies and with the glucagon-like peptide-1 receptor agonist class

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