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Synopsis of the original article ***Liraglutide for Children 6 to <12 Years of Age with Obesity — A Randomized Trial***

Fox CK, et al. *N Engl J Med* 2024; doi: 10.1056/NEJMoa2407379

Synopsis created and reviewed by Novo Nordisk

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Introduction



- No medications are currently approved for the treatment of non-monogenic obesity in children younger than 12 years of age
- The aim of the SCALE Kids study was to evaluate once-daily subcutaneous liraglutide 3.0 mg (or maximum tolerated dose) versus placebo, as an adjunct to lifestyle interventions, in children 6 to younger than 12 years of age with obesity

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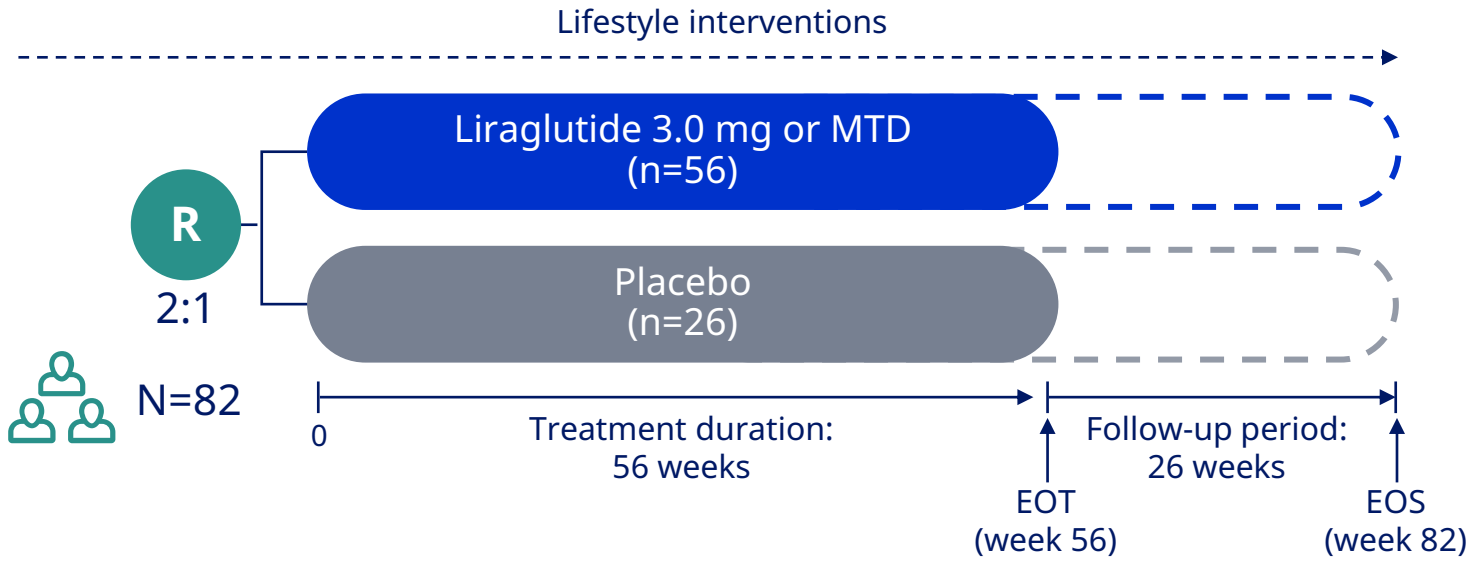
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SCALE Kids study design

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Study design

Randomised phase 3a study comparing once-daily subcutaneous liraglutide 3.0 mg (or MTD) versus placebo, plus lifestyle interventions, for 56 weeks followed by a 26-week follow-up period



Participants

Children 6 to younger than 12 years of age with obesity

Primary endpoint

Percentage change in BMI

Confirmatory secondary endpoints

Percentage change in body weight;
proportion of participants with BMI reduction ≥5%

BMI, body mass index; EOS, end of study; EOT, end of treatment; MTD, maximum tolerated dose; R, randomisation.
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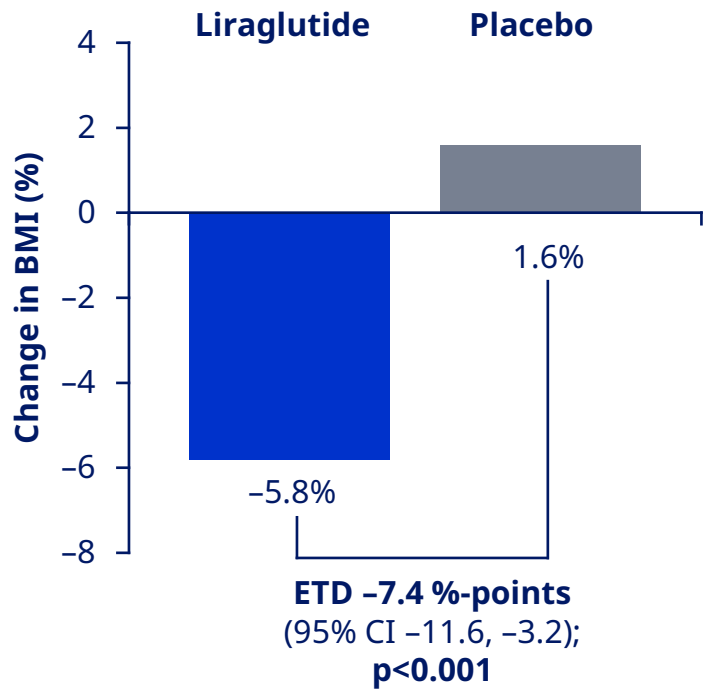
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Liraglutide 3.0 mg provided superior reduction in BMI and body weight versus placebo

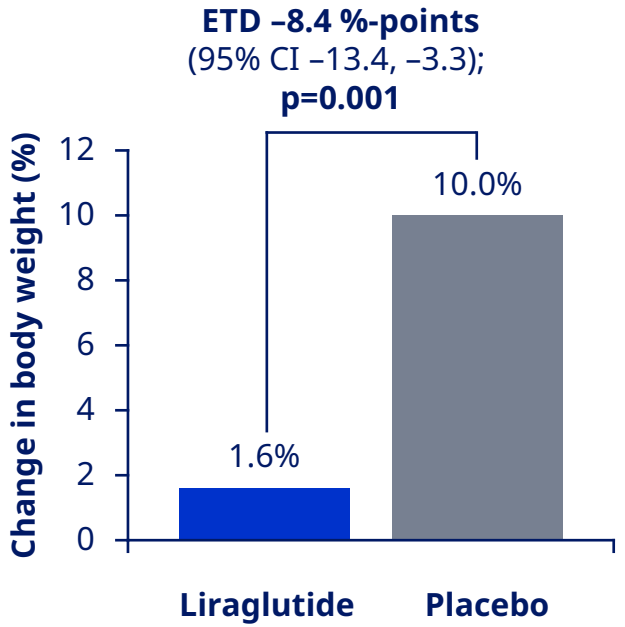
Primary endpoint

Mean percentage change in BMI from baseline to week 56

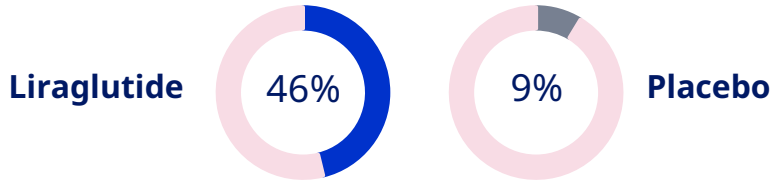


Confirmatory secondary endpoints

Mean percentage change in body weight from baseline to week 56



Proportion of participants with BMI reduction ≥5% at week 56



OR 6.3 (95% CI 1.4, 28.8); **p=0.02**

Safety

Adverse events occurred in:

- **89%** of participants with **liraglutide** and **88%** with **placebo**

Serious adverse events occurred in:

- **12%** of participants with **liraglutide** and **8%** with **placebo**

Most were **gastrointestinal** in nature

BMI, body mass index; CI, confidence interval; ETD, estimated treatment difference; MTD, maximum tolerated dose.
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Conclusions



In children 6 to younger than 12 years of age with obesity, treatment with **liraglutide 3.0 mg** (or the MTD) for 56 weeks plus lifestyle interventions resulted in a greater **reduction in BMI** than placebo plus lifestyle interventions

MTD, maximum tolerated dose.

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