

press release

Novo Nordisk STEP Young phase 3 data: 40.4% of children living with obesity achieved a BMI below the obesity threshold with semaglutide and lifestyle modification

Data highlights

- The STEP Young phase 3 trial met its primary endpoint, demonstrating greater body mass index (BMI) reduction in children aged 6 to under 12 treated with once-weekly subcutaneous semaglutide compared with placebo
- Both groups received lifestyle modification throughout the trial, including reduced-calorie diet and increased physical activity
- 40.4%* of the children treated with semaglutide were no longer classified as having obesity** after 68 weeks compared with non (0%) treated with placebo
- The overall safety and tolerability of semaglutide were consistent with those seen in adults and adolescents trials with semaglutide

Bagsværd, Denmark, 7 September 2026 – Novo Nordisk today announced first results from the STEP Young phase 3 trial, evaluating once-weekly semaglutide in combination with a reduced-calorie diet and increased physical activity in children aged 6 to under 12 years old with obesity. Obesity prevalence is growing in this age group, for whom there are limited clinically tested and approved treatments available when lifestyle modifications are not sufficient.

At baseline, more than 85% of the children had either class II or III severe obesity (corresponding to a BMI above or equal to 35 and 40 in adults, respectively). The trial met its primary endpoint demonstrating superior BMI reduction at week 68 in the group taking semaglutide compared with the placebo group. The results showed that 40.4%* of those treated with semaglutide were no longer classified as having obesity** at week 68, compared with none of those treated with placebo. This means that semaglutide helped two out of five of the children reduce their BMI to a normal weight or overweight classification compared with none of the children in the placebo group. Both groups received lifestyle modification throughout the trial, including reduced-calorie diet and increased physical activity.

"Childhood obesity is particularly concerning due to both immediate and enduring impacts on health, including a strong predilection to adult obesity and increased risk for the early emergence of obesity-related complications," said Ania M. Jastreboff, MD, PhD, Professor of Medicine (Endocrinology) and Pediatrics (Pediatric Endocrinology) at the Yale and Director of the Yale Obesity Research Center (Y-Weight). "Most of the children in the STEP Young trial were classified as having severe (class II or III) obesity at baseline, yet treatment with semaglutide resulted in a BMI percentile category below the obesity threshold in approximately 40% of the children within about a year of treatment,"

Children living with obesity experience cardiovascular disease risk factors, alongside depression, eating disorders, and bullying, with studies showing that their quality of life is comparable to children undergoing cancer treatment.¹⁻³ Without effective intervention, childhood obesity strongly tracks into adulthood¹, where obesity-related complications emerge earlier and more severely,¹⁻³ substantially shortening life expectancy.⁴ An estimated 177 million children aged 5 to 19 were living with obesity in 2025, and this figure is projected to rise to 228 million by 2040.⁵

"For children living with obesity and their families, health challenges can begin early and affect wellbeing throughout life," said Martin Holst Lange, executive vice president, chief scientific officer and head of Research & Development at Novo Nordisk. "As a pioneer in paediatric obesity medicine, we are encouraged by the positive STEP Young results and semaglutide's potential to help children living with obesity who need medical treatment, alongside lifestyle changes, to better manage their obesity. This may prevent serious health risks later in life."

The overall safety and tolerability of semaglutide observed in STEP Young were consistent with previous Novo Nordisk paediatric and adult trials with semaglutide and liraglutide, and no new safety concerns were identified. Furthermore, no safety concerns were identified for growth or pubertal development.

Detailed STEP Young results will be presented at The Obesity Society's annual meeting Obesity-Week 2026, 14-17 November in Washington DC, United States.

* Based on the trial product estimand: treatment effect if all children adhered to treatment

**Based on CDC.gov sex- and age-specific BMI growth charts. Using percentiles to define BMI categories in children is important because they are still growing. In children, obesity is defined as a BMI at or above the 95th percentile for age and sex. Obesity classes II and III in children are defined as a BMI $\geq 120\%$ and $\geq 140\%$ of the 95th percentile, respectively.

About the STEP Young trial

The STEP Young trial is conducted according to regulatory authorities' post marketing requirements for the semaglutide clinical phase 3 development program thus follows the phase 3 results of semaglutide 2.4 mg in adults and adolescents with obesity.

The phase 3 STEP Young is a randomised, double-blind, placebo-controlled, multinational trial investigating safety and efficacy of semaglutide compared with placebo in 165 children with obesity aged 6 to <12 years, both in combination with reduced-calorie diet and increased physical activity. The children received a maximum dose of either 1.7 mg or 2.4 mg of semaglutide, based on their weight at the start of the trial.

Endpoint	Description	Population	Timepoint
Primary endpoint	Change in BMI (%) from baseline (week 0) to week 68	Children aged 6 to under 12 years	Week 68
Confirmatory secondary endpoint	Improvement in BMI classification** from baseline to week 68	Children aged 6 to under 12 years	Week 68
Supportive secondary endpoints	Changes in anthropometric measures, cardiovascular risk factors, glucose metabolism, and body composition (DXA subgroup)	Children aged 6 to under 12 years	Week 68 / Week 104

**Based on CDC.gov sex- and age-specific BMI growth charts. Using percentiles to define BMI categories in children is important because they are still growing. In children, obesity is defined as a BMI at or above the 95th percentile for age and sex. Obesity classes II and III in children are defined as a BMI $\geq 120\%$ and $\geq 140\%$ of the 95th percentile, respectively.

About semaglutide

Semaglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist that mimics the effects of the naturally occurring hormone GLP-1, which regulates blood sugar and body weight. Semaglutide has been tested in several robust clinical development programmes and outcome studies in cardiometabolic diseases, including type 2 diabetes, obesity, cardiovascular disease, heart failure, chronic kidney disease, liver disease, and other related cardiometabolic diseases. Semaglutide is marketed under the brand names Wegovy® (injection or tablet), Ozempic® (injection or tablet), and Rybelsus® (tablet).

About Novo Nordisk

Novo Nordisk is a leading global healthcare company founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat serious chronic diseases built upon our heritage in diabetes. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 66,700 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, [Facebook](#), [Instagram](#), [X](#), [LinkedIn](#) and [YouTube](#).

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References

1. Hampl SE, Hassink SG, Skinner AC, et al. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity. *Pediatrics* 2023; 151
2. Kumar S, Kelly AS. Review of Childhood Obesity: From Epidemiology, Etiology, and Comorbidities to Clinical Assessment and Treatment. *Mayo Clin Proc* 2017; 92: 251-65.

3. Schwimmer JB, Burwinkle TM, Varni JW. Health-related quality of life of severely obese children and adolescents. *Jama* 2003; 289: 1813-9.
4. Wiedemann UCH, van den Akker ELT, Barber TM, et al. Early-Onset of Obesity Model: Impact of Early-Onset Obesity on Comorbidity Risk and Life Expectancy. *Obes Facts* 2026; 19: 265-79.
5. World Obesity Federation. World Obesity Atlas 2026. Available at: https://s3-eu-west-1.amazonaws.com/wof-files/WOF_Obesity_Atlas_2026.pdf (accessed August 2026)