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Synopsis of the original article ***Efficacy and safety of monlunabant in adults with obesity and metabolic syndrome: a double-blind, randomised, placebo-controlled, phase 2a trial***

Knop FK, et al. Lancet Diabetes Endocrinol 2025.
DOI: 10.1016/S2213-8587(25)00216-5

Synopsis created and reviewed by Novo Nordisk

Introduction

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Monlunabant is a novel **CB1R inverse agonist** that has demonstrated encouraging results for weight loss and tolerability

This study investigated the **efficacy** and **safety** of monlunabant in people with **obesity** and **metabolic syndrome**

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CB1R, cannabinoid receptor 1

Study design

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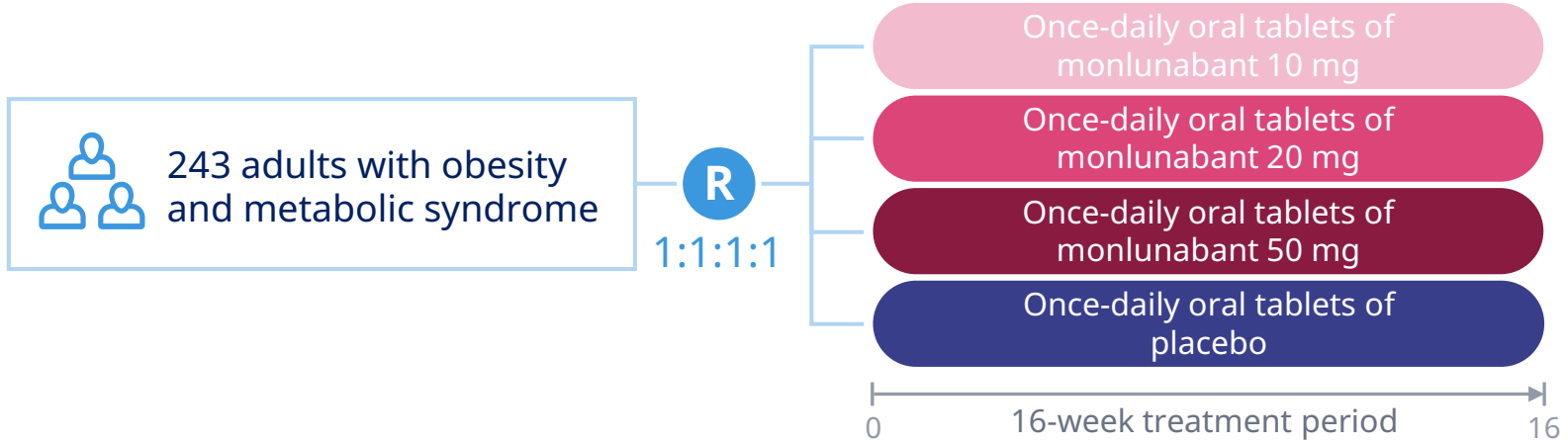
Trial design

Phase 2a, randomised, double-blind, placebo-controlled, dose-ranging trial (NCT05891834)



Primary endpoint

- Change from baseline to week 16 in bodyweight (kg)
- The primary endpoint was assessed in all eligible randomised participants

Safety

- The safety analysis was performed for all randomised participants receiving at least one dose of trial product

R, randomised

Efficacy

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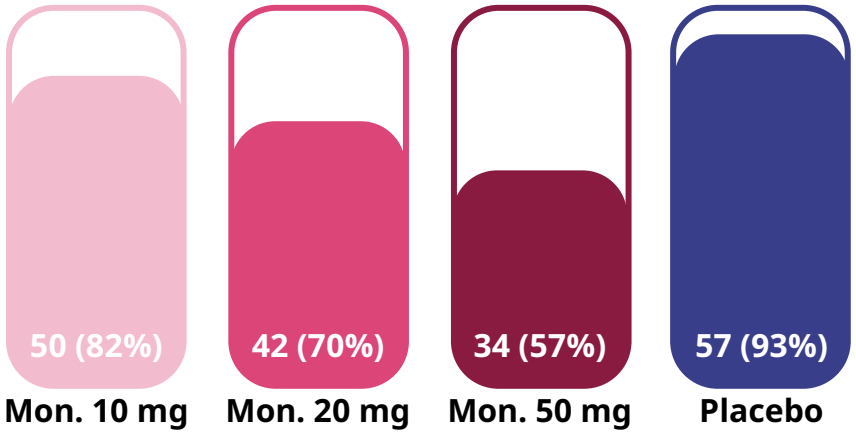
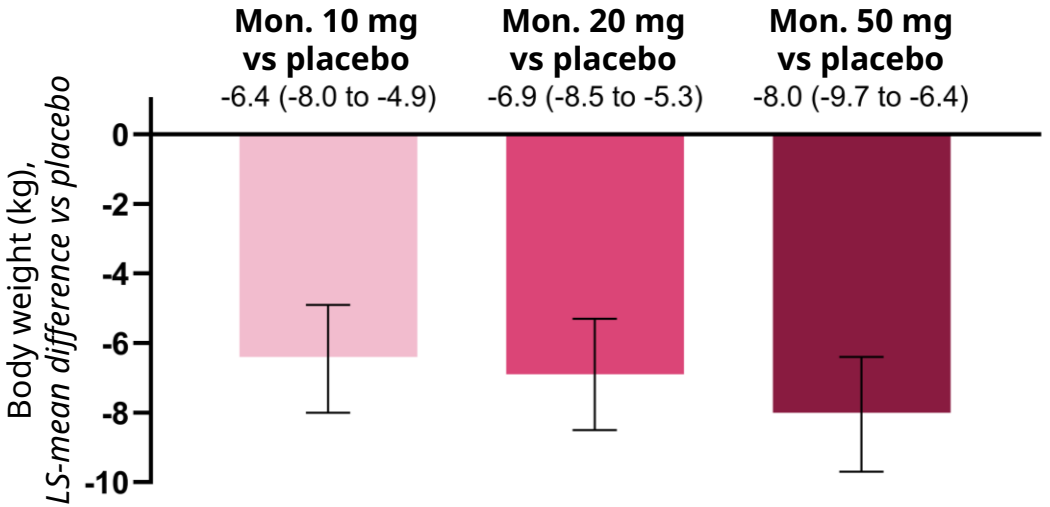
183 (76%) of 242 participants completed the trial



N (%) participants completing the trial

Participants receiving monlunabant showed **statistically significant and clinically meaningful weight loss** compared to placebo



Error bars are 95% confidence intervals

Mon, monlunabant; LS-mean, least squares mean.

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Safety

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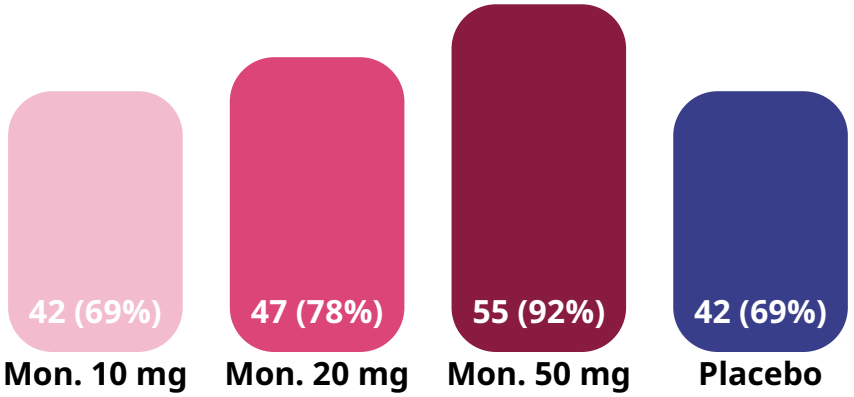
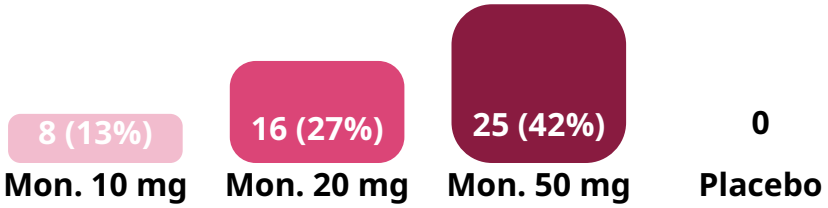
Adverse events were mostly mild to moderate **gastrointestinal** and **psychiatric disorders**



N (%) participants reporting adverse events

Withdrawals due to adverse events appeared **dose-dependent**, and were driven by nausea, anxiety, diarrhoea, irritability, and sleep disorder



N (%) participants withdrawing due to adverse events

Mon, monlunabant.

Conclusion

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Participants receiving monlunabant showed **statistically significant and clinically meaningful weight loss** compared with those receiving placebo for all tested doses

Only slightly greater weight loss was observed at higher doses, whereas **adverse events appeared dose dependent**

Further investigation is needed to assess the safety and efficacy of lower doses of monlunabant, to evaluate its potential as a medication for obesity

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