

1. [Liraglutide reverses pronounced insulin-associated weight gain, improves glycaemic control and decreases insulin dose in patients with type 2 diabetes: a 26 week, randomised clinical trial \(ELEGANT\)](#)

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Abstract

Aims/hypothesis: The best treatment strategy for a patient with type 2 diabetes who shows pronounced weight gain after the introduction of insulin treatment is unclear. We determined whether addition of a glucagon-like peptide-1 (GLP-1) analogue could reverse pronounced insulin-associated weight gain while maintaining glycaemic control, and compared this with the most practised strategy, continuation and intensification of standard insulin therapy.

Methods: In a 26-week, randomised controlled trial (ELEGANT), conducted in the outpatient departments of one academic and one large non-academic teaching hospital in the Netherlands, adult patients with type 2 diabetes with $\geq 4\%$ weight gain during short-term (≤ 16 months) insulin therapy received either open-label addition of liraglutide 1.8 mg/day ($n = 26$) or continued standard therapy ($n = 24$). A computer-generated random number list was used to allocate treatments. Participants were evaluated every 4-6 weeks for

weight, glycaemic control and adverse events. The primary endpoint was between-group weight difference after 26 weeks of treatment (intention to treat).

Results: Of 50 randomised patients (mean age 58 years, BMI 33 kg/m²), HbA1c 7.4% [57 mmol/mol]), 47 (94%) completed the study; all patients were analysed. Body weight decreased by 4.5 kg with liraglutide and increased by 0.9 kg with standard therapy (mean difference -5.2 kg [95% CI -6.7, -3.6 kg]; $p < 0.001$). The respective changes in HbA1c were -0.77% (-8.4 mmol/mol) and +0.01% (+0.1 mmol/mol) (difference -0.74% [-8.1 mmol/mol]) ([95% CI -1.08%, -0.41%] [-11.8, -4.5 mmol/mol]; $p < 0.001$); respective changes in insulin dose were -29 U/day and +5 U/day (difference -33 U/day [95% CI -41, -25 U/day]; $p < 0.001$). In five patients (19%), insulin could be completely discontinued. Liraglutide was well tolerated; no severe adverse events or severe hypoglycaemia occurred.

Conclusions/interpretation: In patients with pronounced insulin-associated weight gain, addition of liraglutide to their treatment regimen reverses weight, decreases insulin dose and improves glycaemic control, and hence seems a valuable therapeutic option compared with continuation of standard insulin treatment. Trial registration ClinicalTrials.gov [NCT01392898](https://clinicaltrials.gov/ct2/show/study/NCT01392898). Funding The study was funded by Novo Nordisk.

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