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Efficacy and Safety of Fast-acting Insulin Aspart are maintained over 52 weeks: Comparison with Insulin Aspart in onset 1

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Aim: The aim of the additional 26-week period was to assess long-term safety and efficacy of faster aspart.
Method: In the initial 26-week treatment period of onset 1, subjects were randomised to either double-blind mealtime fast-acting insulin aspart, insulin aspart or open-label post-meal fast-acting insulin aspart, each with once- or twice-daily insulin detemir. Subjects on mealtime fast-acting insulin aspart (n=381) and mealtime insulin aspart (n=380) then continued to the additional 26-week treatment period.
Results: After 52 weeks, mean HbA1c change from baseline was −0.08% with fast-acting insulin aspart and +0.01% with insulin aspart, with significant estimated treatment difference (ETD [95% confidence interval {CI}]) favouring fast-acting insulin aspart (ETD: −0.10% [−0.19;−0.00]). Following a standardised meal test, the change from baseline in 1-h postprandial plasma glucose (PPG) increment significantly favoured fast-acting insulin aspart (−1.05 mmol/L) compared with insulin aspart (−0.14 mmol/LThe improvements in postprandial glucose control were also reflected in 7-9-7-point self-measured plasma glucose profiles (SMPG) at 52 weeks, with significant difference between the two treatment arms in favour of fast-acting insulin aspart for mean overall plasma glucose change from baseline (ETD [95%CI]: −0.23 mmol/L [−0.46;−0.00]; −4.14 mg/dL [−8.23;−0.06]), driven by 2-h PPG increments after breakfast and dinner. At the end of the trial, median total insulin dose was 61.3 U/0.77 U/kg with fast-acting insulin aspart and 68.5 U/0.83 U/kg with insulin aspartAfter 52 weeks, the overall safety profiles, including adverse events, immunogenicity and standard safety parameters, were similar between fast-acting insulin aspart and insulin aspart, and as expected for insulin aspart.