Efficacy and safety of continuous subcutaneous insulin infusion of fast-acting insulin aspart compared with insulin aspart in type 1 diabetes

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onset 5, a double-blind, treat-to-target trial, evaluated the efficacy and safety of fast-acting insulin aspart (faster aspart), regardless of treatment discontinuation, in continuous subcutaneous insulin infusion (CSII). Following a 4-week run-in on pre-trial insulin, subjects (n=472) with type 1 diabetes (T1D) were randomised to 16 weeks of treatment with CSII to either faster aspart (n=236) or insulin aspart (IAsp, n=236). Non-inferiority of faster aspart to IAsp for the change from baseline in HbA1c (primary endpoint) using a pre-specified margin of 0.4% was confirmed. Mean HbA1c changed from 7.5% at baseline to 7.4% (faster aspart) and 7.3% (IAsp) with an estimated treatment difference (ETD) of 0.09% [95% CI: 0.01;0.17] (1.0 mmol/mol [0.14;1.87]). Faster aspart was superior to IAsp in 1-h postprandial plasma glucose (PPG) increment after a standardised meal test (78 g carbs) (ETD [95% CI] –0.91 mmol/L [–1.43;–0.39]) with statistically significant reductions also at 30 min (ETD [95% CI] –0.66 mmol/L [–1.00;–0.31]) and 2 h (ETD [95% CI] –0.90 mmol/L [–1.58;–0.22]). The improvement in PPG was also reflected in the mean 1-h interstitial glucose increment after all meals (ETD [95% CI] −0.21 mmol/L [−0.31;−0.11]). There was no statistically significant difference in the overall rate of severe or confirmed hypoglycaemia (plasma glucose <3.1 mmol/L). A numerical imbalance in severe hypoglycaemic episodes between faster aspart and IAsp was seen in the treatment (21 vs. 7) and run-in period (4 vs. 0). Faster aspart provides an effective and safe option for CSII treatment in subjects with T1D.