Fiasp: a new faster-acting insulin aspart formulation for diabetes

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Fiasp is a new faster-acting formulation of insulin aspart that is absorbed more quickly than conventional insulin aspart (NovoRapid) following mealtime administration. This article describes its properties, efficacy and adverse effects.

Basal-bolus insulin therapy is recommended as the insulin regimen of choice for adults with type 1 diabetes and as an option in those with type 2 diabetes. The fast-acting component should be an insulin analogue rather than a human insulin, and this should be given before meals to reduce the meal-associated rapid rise in blood glucose. An insulin pump is an alternative for those unable to achieve target HbA1c using multiple daily injections or when attempts to do so are associated with disabling hypoglycaemia. Of all the fast-acting insulin analogues available, insulin aspart accounts for 76% of prescriptions dispensed in primary care in England.

Fiasp is a faster-acting insulin aspart formulation that is absorbed more quickly than conventional insulin aspart (NovoRapid), resulting in earlier occurrence of insulin in the blood (by five minutes), a 74% greater early glucose-lowering effect and an earlier offset (by 12–14 minutes) (see Figure 1). The increased speed of absorption is due to the addition of nicotinamide (vitamin B3) to the formulation; L-arginine is also added to boost stability.

Administration and dosing

Fiasp is licensed for the treatment of diabetes in adults and is either injected subcutaneously as part of a basal-bolus regimen or used for continuous subcutaneous infusion via an insulin pump. When used as part of a basal-bolus regimen, it should be administered up to two minutes before the start of the meal (with the option to administer up to 20 minutes after starting the meal) in combination with an intermediate- or long-acting insulin given at least once a day. It would normally account for approximately 50% of the insulin requirement in a basal-bolus regimen.

Patients using a different fast-acting mealtime insulin can transfer to Fiasp on a unit-to-unit basis; a subsequent change in dose, and in the dose and timing of the intermediate- or long-acting insulin, may be needed and blood glucose levels should be monitored closely. No dose adjustment is recommended for older people (there is limited experience in those aged 75 years and over). As with other insulins, renal or hepatic impairment may reduce the insulin requirement.

Efficacy

Fiasp has been compared with NovoRapid in people with type 1 (ONSET 1, n=1143) or type 2 (ONSET 2, n=689) diabetes in two 26-week trials, and with a basal-only regimen in people with type 2 diabetes.
2 diabetes in an 18-week trial (ONSET 3, n=236).9

In these trials, mean baseline HbA1c was 60–64 mmol/mol (7.6%–8.0%) despite treatment with a basal insulin plus, in those with type 2 diabetes, oral hypoglycaemic drugs including metformin. The primary endpoint was the change from baseline in HbA1c.

In ONSET 1, patients with type 1 diabetes (mean ages 44–46 years) were randomised to treatment with Fiasp (administered before or after meals) or to mealtime NovoRapid, plus basal therapy with insulin detemir. Median insulin bolus doses were similar (about 30 units). Both regimens of Fiasp were noninferior to NovoRapid for reduction in HbA1c,

postprandial glucose levels after one and two hours were significantly lower with mealtime Fiasp compared with NovoRapid but significantly higher with postmeal Fiasp. In a 26-week extension phase, HbA1c increased slightly with Fiasp and NovoRapid but remained similar; postprandial glucose was significantly lower with Fiasp only at one hour.10

In ONSET 2, patients with type 2 diabetes (mean age 60 years) were randomised to treatment with mealtime Fiasp or NovoRapid; basal therapy was with insulin glargine and metformin. Median insulin bolus doses were 43–46 units. Both regimens reduced HbA1c and Fiasp was non-inferior to NovoRapid. Postprandial glucose was significantly lower with Fiasp after one hour but not after two to four hours.

In both ONSET 1 and ONSET 2, the proportions of patients with HbA1c <53 mmol/mol without severe hypoglycaemia were similar with Fiasp and NovoRapid in type 1 diabetes (25–30%) and type 2 diabetes (about 70%).

In ONSET 3, bolus administration of Fiasp added to basal insulin plus metformin significantly reduced HbA1c and postprandial glucose in patients with type 2 diabetes. This was associated with an increase in hypoglycaemia (12.8 vs 2.0 episodes per patient-year) and weight gain (1.8 vs 0.2 kg), consistent with the increase in total insulin dose (from 0.6 to 1.2 units/kg).

Fiasp was compared with NovoRapid for use in an insulin pump in a two-week crossover study (n=43).11 The reduction in

postprandial glucose levels at two hours was significantly greater with Fiasp; mean daily bolus and basal insulin doses and overall glycaemic control was similar.

**Adverse events**

The adverse events associated with Fiasp in clinical trials were typical of a fast-acting insulin and were similar in frequency and severity to NovoRapid except that, based on low numbers, mild injection site reactions may have been more frequent with Fiasp.10 Hypoglycaemia rates were similar overall but postprandial hypoglycaemia was more frequent with Fiasp than NovoRapid in patients with type 1 or type 2 diabetes.10

**References**


**Declaration of interests**

None to declare.

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