

## Insulin glargine as effective as insulin suspension isophane

Insulin glargine is as effective as insulin suspension isophane [NPH insulin], but associated with a lower incidence of nocturnal hypoglycaemia, in patients with type 2 diabetes mellitus who are receiving oral antidiabetic therapy. These were the findings of a randomised study conducted at 29 sites in Europe and South Africa.\*

The study included 204 patients with type 2 diabetes and inadequate glycaemic control on oral antidiabetic medication, who were randomised to treatment with insulin glargine with 30 µg/mL of zinc, insulin glargine with 80 µg/mL of zinc, or NPH insulin. Patients were allocated to the two insulin glargine formulations in a double-blind fashion, whereas the NPH insulin arm of the study was open-label. Doses were titrated over 3 weeks to achieve fasting blood glucose (FBG) levels of 4-7 mmol/L, and then continued at a maintenance dose for 1 week.

At the end of the 4-week study period, adjusted mean fasting plasma glucose levels had decreased significantly versus baseline in all three treatment groups ( $p = 0.0001$ ), but the magnitude of the change was similar in patients receiving insulin glargine and NPH insulin. Similarly, secondary endpoints for glucose control (mean FBG, blood glucose profile, stability of FBG, nocturnal blood glucose, fasting C-peptide, fasting serum insulin, non-esterified fatty acids, glycosylated haemoglobin and fructosamine) all improved significantly from baseline and by a similar magnitude in each treatment group. Mean basal doses increased by around 4U in each group.

All three treatments were well tolerated; adverse events were all mild to moderate in severity and developed in three patients in each of the insulin glargine groups and two patients in the NPH insulin group. However, a significantly higher proportion of patients in the NPH insulin group than the insulin glargine group developed nocturnal hypoglycaemia (both symptomatic and asymptomatic).

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HOE 901/2004 Study Investigators Group. Safety and efficacy of insulin glargine (HOE 901) versus NPH insulin in combination with oral treatment in Type 2 diabetic patients. Diabetic Medicine 20: 545-551, Jul 2003 800950091