Maternal efficacy and safety outcomes in a randomized, controlled trial comparing insulin detemir with NPH insulin in 310 pregnant women with type 1 diabetes.

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**Source**

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**Abstract**

**OBJECTIVE:**

This randomized, controlled noninferiority trial aimed to compare the efficacy and safety of insulin detemir (IDet) versus neutral protamine Hagedorn (NPH) (both with prandial insulin aspart) in pregnant women with type 1 diabetes.

**RESEARCH DESIGN AND METHODS:**

Patients were randomized and exposed to IDet or NPH up to 12 months before pregnancy or at 8-12 weeks gestation. The primary analysis aimed to demonstrate noninferiority of IDet to NPH with respect to A1C at 36 gestational weeks (GWs) (margin of 0.4%). The data were analyzed using linear regression, taking several baseline factors and covariates into account.

**RESULTS:**

A total of 310 type 1 diabetic women were randomized and exposed to IDet (n = 152) or NPH (n = 158) up to 12 months before pregnancy (48%) or during pregnancy at 8-12 weeks (52%). The estimated A1C at 36 GWs was 6.27% for IDet and 6.33% for NPH in the full analysis set (FAS). IDet was declared noninferior to NPH (FAS, -0.06% [95% CI -0.21 to 0.08]; per protocol, -0.15% [-0.34 to 0.04]). Fasting plasma glucose (FPG) was significantly lower with IDet versus NPH at both 24 GWs (96.8 vs. 113.8 mg/dL, P = 0.012) and 36 GWs (85.7 vs. 97.4 mg/dL, P = 0.017). Major and minor hypoglycemia rates during pregnancy were similar between groups.

**CONCLUSIONS:**

Treatment with IDet resulted in lower FPG and noninferior A1C in late pregnancy compared with NPH insulin. Rates of hypoglycemia were comparable.
Comment in

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