

Summary attachment - study ended before 21 July 2013

EudraCT number: 2008-001092-29

Full title of the study: Effect of glimepiride on glycemic control in patients with typ 2 diabetes treated with insulin and metformin

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Study ended: 2011-12-31

Link to published article:

<https://www.sciencedirect.com/science/article/pii/S0168822714000230>

Abstract from published article:

Aims: To investigate the effect on glycaemic control of adding glimepiride to on-going treatment with metformin and insulin in patients with known diabetes more than 10 years.

Methods: Glimepiride 4 mg or placebo was added in randomised order for three months with a washout period of 6 weeks. All insulin regimens were allowed. Insulin doses were reduced if considered necessary. Continuous glucose monitoring was performed at the end of each period.

Results: Forty-three patients, median age 66 years (46–74), diabetes duration 16 (10–30), BMI 30 kg/m² (25–37) and mean HbA1c 7.1% NGSP, (64 mmol/mol IFCC) were randomised. With placebo there was no change in HbA1c while a decrease of 0.6%, (7 mmol/mol IFCC) ($P < 0.001$), was observed with glimepiride even though insulin doses had to be reduced in 23 patients (median change 29%, range 2–100%). Minor hypoglycaemia was reported but no severe hypoglycaemic event was observed. The ratio between C-peptide/glucose increased significantly ($P < 0.001$) with glimepiride, both fasting and postprandially and, in a stepwise multiple regression analysis of possible predictive factors for response, a more pronounced decrease in HbA1c was associated with the magnitude of the increment in C peptide/glucose. Older age was associated with a smaller response. Twenty-nine patients (67%) were defined as responders if this was defined as an HbA1c decrease 0.5% (5 mmol/mol IFCC) or an insulin dose reduction 20%.

Conclusions: Even after long duration of diabetes, addition of glimepiride to insulin and metformin can be effective in lowering HbA1c and/or reducing the need for exogenous insulin.

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