Six-year results from the Early Diabetes Intervention Trial

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The Early Diabetes Intervention Trial (EDIT) randomized 631 people at risk of diabetes with two fasting plasma glucose (FPG) levels 5.5-5.7 mm/L 2-weeks apart in nine UK centres. Glycaemic status (WHO 1985) was also assessed at baseline using the mean of two OGTTs before double-blind 2 x 2 factorial allocation to acarbose 50mg t.d.s. or placebo and Metformin 500mg t.d.s. or placebo with 6-year follow-up. At entry, subjects were 49% male, 94% Caucasian, mean (SD) 52.1 (10.0) years, body mass index 28.6 (4.5) kg/m², FPG 6.0 (0.5) mm/L, HbA1c 5.9 (0.5)%; 17% had 2-hour plasma glucose > 11.0 mm/L, 37% IGT, 21% IFG and 46% NGT. By 6 years 31% were diabetic and 14% discontinued follow-up. Of the remaining 339, 37% vs. 46% (P = 0.099) were taking acarbose compared with placebo, 39% vs. 44% (P = 0.38) Metformin compared with placebo. No differences were seen in relative risk for diabetes by 6 years with acarbose (1.04, P = 0.81), Metformin (0.99, P = 0.94) or combination therapy (1.02, P = 0.91). In those with IGT at baseline, relative risk was reduced significantly with acarbose (0.66, P = 0.046) but not Metformin (1.09, P = 0.70) or combination therapy (0.72, P = 0.27). The ability of therapies to reduce risk of diabetes may differ for those with IGT or IFG.