UK Prospective Diabetes Study (UKPDS). VIII. Study design, progress and performance.

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The UK Prospective Diabetes Study (UKPDS) is a multi-centre, prospective, randomised, intervention trial of 5100 newly-diagnosed patients with Type 2 (non-insulin-dependent) diabetes mellitus which aims to determine whether improved blood glucose control will prevent complications and reduce the associated morbidity and mortality. Newly presenting Type 2 diabetic patients aged 25-65 years inclusive, median age 53 years, median body mass index 28 kg/m2 and median fasting plasma glucose 11.3 mmol/l, were recruited and treated initially by diet. Ninety five percent remained hyperglycaemic (fasting plasma glucose greater than 6 mmol/l) and were randomly allocated to different therapies. In the main randomisation, those who were asymptomatic and had fasting plasma glucose under 15 mmol/l were allocated either to diet policy, or to active policy with either insulin or sulphonylurea aiming to reduce the fasting plasma glucose to under 6 mmol/l. Over 3 years, the median fasting plasma glucose in those allocated to diet policy was 8.9 mmol/l compared with 7.0 mmol/l in those allocated to active policy. The Hypertension in Diabetes Study has been included in a factorial design to assess whether improved blood pressure control will be advantageous. Patients with blood pressure greater than or equal to 160/90 mm Hg were randomly allocated to tight control aiming for less than 150/85 mm Hg with either an angiotensin-converting enzyme inhibitor or a Beta-blocker or to less tight control aiming for less than 200/105 mm Hg. The endpoints of the studies are major clinical events which affect the life and well-being of patients, such as heart attacks, angina, strokes, amputations, blindness and renal failure. To date, 728 patients have had at least one clinical endpoint. Surrogate endpoints include indices of macrovascular and microvascular disease detected by ECG with Minnesota Coding, retinal colour photography and microalbuminuria. The studies also aim to evaluate potential risk factors for the development of diabetic complications such as smoking, obesity, central adiposity, plasma LDL- and HDL-cholesterol, triglyceride, insulin, urate and other biochemical variables. The studies are planned to terminate in

1994, with a median follow-up of 9 years (range 3-16 years) for the glucose study and 5 years (range 2-6 years) for the hypertension study.