

Rationale, design and recruitment characteristics of a large, simple international trial of diabetes prevention: the DREAM trial.

The DREAM Trial Investigators

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Aims/hypothesis: Diabetes is a rapidly rising independent risk factor for atherosclerosis and serious illness. This risk can be reduced by lifestyle changes and/or various drugs. Novel therapies to prevent diabetes, as well as new risk factors for diabetes, atherosclerosis and obesity require testing and identification.

Methods: People with impaired fasting glucose or impaired glucose tolerance were randomized to ramipril (15 mg/day) or placebo and rosiglitazone (8 mg/day) or placebo with a 2x2 factorial design. They are assessed semi-annually for the primary outcome (diabetes or death). Diabetes is diagnosed if two consecutive plasma glucose levels exceed diagnostic thresholds (i.e. fasting ≥ 7.0 mmol/l or 2-h ≥ 11.1 mmol/l) within a 3-month period. Assuming an annual primary outcome incidence of 5%, there is more than 90% power to detect a 22% reduction. Approximately 20% of participants are having annual carotid ultrasounds to assess the effects on atherosclerosis. Patients screened but not randomized are being followed prospectively to identify determinants of obesity, diabetes and related disorders.

Results: A total of 24,872 individuals in 21 countries were screened over 2 years and are eligible for follow-up. Of these, 5269 were randomized: 1835 (35%) had isolated impaired fasting glucose tolerance, 739 (14%) had isolated impaired fasting glucose, and 2692 (51%) had both disorders. Annual carotid ultrasounds are currently being performed in 1406 randomised individuals.

Conclusions/interpretations: The DREAM trial and related studies will determine if ramipril or rosiglitazone reduces the number of cases of diabetes and atherosclerosis, and will identify novel risk factors for diabetes.