

Prevention of Type 1 Diabetes Mellitus

AMERICAN DIABETES ASSOCIATION

BACKGROUND — Type 1 diabetes mellitus is an autoimmune disease. Although the process by which the pancreatic β -cell is destroyed is not well understood, several risk factors and immune-related markers are known that accurately identify many first-degree relatives of patients with type 1 diabetes who will develop the disease. Because we now have the ability to predict the development of type 1 diabetes in some people, investigators have begun to explore the use of intervention therapy to halt or even prevent β -cell destruction in such individuals.

STATEMENT

General information

- Sufficient data exist to warrant intervention studies for the prevention of type 1 diabetes.
- Intervention for the prevention of type 1 diabetes should be attempted only in the context of defined clinical studies with Institutional Review Board oversight.
- Intervention studies for the prevention of type 1 diabetes are best accomplished by randomized controlled studies.

- A registry of intervention studies should be maintained, and all planned studies should be reported to a coordinating body.

Screening

- Screening of any population is discouraged outside the context of defined research studies.
- Screening of high-risk individuals (e.g., first-degree relatives of type 1 diabetic patients) should be encouraged, providing that individuals who screen positive are referred to centers participating in cooperative intervention studies or other scientific investigations. Information about ongoing studies should be easily obtainable.
- All patients screened and not entered into a study should be counseled as to their risk of diabetes, and follow-up should be offered.
- Screening by determining HLA type is not currently warranted outside the context of defined research studies.

An NIH-sponsored multicenter study, the Diabetes Prevention Trial 1 (DPT-1), de-

signed to determine whether the development of type 1 diabetes can be prevented or delayed has just been partially completed. The DPT-1 was designed to determine if low-dose insulin administered either by injections or orally could delay or prevent type 1 diabetes in people with a significantly increased risk of developing the disease within 5 years. This large multicenter trial was based on animal studies and a small trial in humans indicating that insulin given could prevent type 1 diabetes. The DPT-1 trial randomly assigned 339 individuals deemed to be at *high risk* (>50% risk) for disease development based on signs of autoimmune β -cell destruction and low insulin response to an intravenous glucose challenge to receive insulin or to serve as control subjects. The rate of development of diabetes was identical (60%) in both groups, indicating the injection of low-dose insulin does not delay or prevent type 1 diabetes. A second arm of the DPT-1 trial using oral insulin in those deemed to be at *moderate risk* (25-50% risk) of developing diabetes is ongoing.

A coordinating body has been funded to evaluate and sponsor new intervention initiatives and to maintain a registry of such trials.



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