Researchers have begun a clinical study of oral insulin to prevent or delay type 1 diabetes in at-risk people, the National Institutes of Health (NIH) announced today. Type 1 Diabetes TrialNet, an NIH-funded network of researchers dedicated to the understanding, prevention, and early treatment of type 1 diabetes, is conducting the study in more than 100 medical centers across the United States, Canada, Europe, and Australia.

“Our goal is to prevent type 1 diabetes or to delay it as long as possible. If diabetes can be delayed, even for several years, those at risk will be spared the difficult challenges of controlling glucose and the development of complications for that much longer,” said TrialNet study chair Jay Skyler, M.D., of the University of Miami.

In the study, researchers are testing whether an insulin capsule taken by mouth once a day can prevent or delay diabetes in a specific group of people at risk for type 1 diabetes. An earlier trial suggested that oral insulin might delay type 1 diabetes for about four years in some people with autoantibodies to insulin in their blood. Animal studies have also suggested that insulin taken orally may prevent type 1 diabetes. Some scientists think that introducing insulin via the digestive tract induces tolerance, or a quieting of the immune system. Insulin taken orally has no side effects because the digestive system breaks it down quickly. To lower blood glucose, insulin must be injected or administered by an insulin pump.

In type 1 diabetes, a person’s own immune cells destroy the beta cells of the pancreas. Beta cells sense blood glucose and produce the hormone insulin, which regulates glucose and converts it to energy. The immune attack on beta cells begins well before a person develops diabetes and continues long after the disease is diagnosed. In the early stages of autoimmunity, up to 10 years before diabetes is diagnosed, autoantibodies may appear in the blood. These autoantibodies to glutamate decarboxylase (GAD), IA-2, and to insulin itself indicate a greater risk for developing type 1 diabetes. For a person with high-risk genes and all three antibodies, the risk of developing diabetes in the next 5 years is greater than 50 percent.
First- and second-degree relatives of people with type 1 diabetes who may be at risk are being screened through TrialNet’s natural history study, which is examining the immune and metabolic events that precede diabetes symptoms. Screening involves a simple blood test for the autoantibodies that signify diabetes risk. Individuals enrolled in the natural history study are closely monitored for diabetes development and may be eligible to participate in the oral insulin trial or future studies that try to arrest the autoimmune process.

Studies for the Newly Diagnosed

TrialNet studies are also aimed at safely preserving insulin production in people recently diagnosed with type 1 diabetes. In the few months after diagnosis, most patients still have a supply of functioning beta cells that, with the help of insulin injections, contribute to good control of blood glucose. If beta cells can be protected, more patients would be able to tightly control their blood glucose, which prevents or delays damage to the eyes, nerves, kidneys, heart, and blood vessels.

One TrialNet study seeks to turn off the immune attack on beta cells with Rituximab, a monoclonal antibody that binds to and temporarily destroys a specific class of immune cells. The Rituximab trial is recruiting patients with type 1 diabetes diagnosed within the previous 3 months. Rituximab is approved by the Food and Drug Administration (FDA) to treat specific forms of lymphoma and moderate to severe rheumatoid arthritis. It is not approved for the prevention of type 1 diabetes.

Also under way is a study testing whether mycophenolate mofetil (MMF) or MMF plus daclizumab (DZB), drugs approved by FDA to prevent rejection after an organ transplant, can slow or arrest the autoimmunity of type 1 diabetes. This study has recruited the needed number of patients.

Study for Newborns at Risk for Type 1 Diabetes

The Nutritional Intervention to Prevent Type 1 Diabetes (NIP) Trial is a pilot study of docosahexaenoic acid (DHA), an omega-3 fatty acid that may have anti-inflammatory benefits that prevent development of the autoimmunity that leads to type 1 diabetes. The NIP study is being conducted in:

- babies less than 5 months old who have immediate family members with type 1 diabetes, and
- pregnant mothers in their third trimester whose babies are at risk for type 1 diabetes, either because the mother has type 1 diabetes herself or other immediate relatives have the disease.

About 5 to 10 percent of the nearly 21 million people with diabetes have type 1, formerly known as juvenile onset diabetes or insulin-dependent diabetes. Type 1 diabetes tends to arise in children and young adults but is also diagnosed in older people. Patients need three or more insulin injections a day or treatment with an insulin pump to maintain blood glucose control. To prevent complications, they must regularly monitor their blood glucose, striving for a range that is as close to normal as possible. The constant challenge of managing the disease poses an enormous burden on patients and their families.
The Type 1 Diabetes TrialNet studies are funded by the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Child Health and Human Development, and the National Institute of Allergy and Infectious Diseases within the NIH. The Juvenile Diabetes Research Foundation International and the American Diabetes Association also support the initiative.

For more information about TrialNet studies, see http://www.diabetestrialnet.org/ [1] or call 1-800-HALT-DM1 (1-800-425-8361).

*The NIDDK, a component of the NIH, conducts and supports research in diabetes and other endocrine and metabolic diseases; digestive diseases, nutrition, and obesity; and kidney, urologic and hematologic diseases. Spanning the full spectrum of medicine and afflicting people of all ages and ethnic groups, these diseases encompass some of the most common, severe, and disabling conditions affecting Americans. For more information about NIDDK and its programs, see http://www.niddk.nih.gov/.[2].*

The National Institutes of Health (NIH) ? The Nation’s Medical Research Agency ? includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov [3].

For more information about these studies and other diabetes related clinical trials being conducted at the University of California, San Francisco, please contact: Kathleen Fraser at 415-353-9084 or email kfraser@diabetes.ucsf.edu [4].

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[4] mailto:kfraser@diabetes.ucsf.edu