

The Most Important Piece of the Puzzle in Curing Diabetes Is You

TrialNet is a network of 18 Clinical Centers working in cooperation with screening sites throughout the United States, Canada, Finland, United Kingdom, Italy, Germany, Australia, and New Zealand. This network is dedicated to the study, prevention, and early treatment of type 1 diabetes. TrialNet is supported by the United States National Institutes of Health and Department of Health & Human Services, Juvenile Diabetes Research Foundation International (JDRF), and the American Diabetes Association.

Information for both patients and physicians about all TrialNet studies can be found on their Web site at www.diabetestrialnet.org.

ONGOING STUDIES

Currently recruiting

- The Natural History Study of the Development of Type 1 Diabetes will study people at increased risk for

type 1 diabetes to learn more about how type 1 diabetes occurs.

- The Oral Insulin for Prevention of Type 1 Diabetes Study has launched a clinical study of oral insulin to prevent or delay type 1 diabetes in at-risk people. The goal is to prevent type 1 diabetes or to delay it as long as possible.

- The Nutritional Intervention to Prevent Type 1 Diabetes Study will help us learn more about a dietary substance, docosahexaenoic acid (DHA), when given to pregnant mothers in their third trimester and infants aged <5 months. This research is being done as a pilot study.

- The Type 1 Diabetes Genetics Consortium (T1DGC) (www.t1dgc.org) is a group of diabetes researchers from around the world who have come together to collect blood samples and information from families with type 1 diabetes.

Current JDRF-funded Human Clinical Trials

Autoimmunity

- Umbilical Cord Blood (phase 1)
- hOKT3 gamma (Ala-Ala) (phase 2)
- Pro-insulin (phase 1)
- Rituximab (phase 2)
- Tolerx TRX4 anti-CD3 (phase 2/3)
- MacroGenics MGA031 anti-CD3 (phase 2/3)
- Osiris Prochymal (phase 2)

Replacement

- Beta Cell Allografts (phase 1/2)
- Islet Transplant (Hering/Stock) (phase 1/2)
- Islet Transplant (Alejandro Ricordi) (phase 1/2)
- Islet Transplant (Larsen Weber) (phase 1/2)
- Islet Transplant (Naji) (phase 1/2)
- Tolerance induction (phase 1/2)
- ECIT (phase 1/2)
- Encapsulated (phase 1/2)
- Islet Transplant (Australian) (phase 1/2)
- CNI-Sparing (phase 1/2)

Regeneration

- Transition Therapeutics GLP-1 & Gastrin (phase 2)

Complications

- Sympathetic (phase 1)
- Hypoglycemia (phase 1)
- Preventing Hypoglycemia (phase 1)
- Responses of Glucagon (phase 1)
- Cox-2 Inhibition (phase 1)
- Insulin Pump Therapy (phase 1)
- ALT-711 (phase 1)
- Sangamo SB-509 for Diabetic Neuropathy (phase 2)
- Ranibizumab for Diabetic Macular Edema (phase 2)
- CoMentis ATG-3 for Diabetic Macular Edema (phase 2)

Metabolic Control

- Continuous Glucose Sensor Trials (phase 3)
- Closed Loops Proof-of-Concept Trials (phase 1)

Prevention

- Oral Insulin (phase 2)
- INIT-II (phase 2)
- Pre-POINT (phase 1)

No longer recruiting

- The Rituximab Study (Anti-CD20). This study is investigating the possibility of stopping or slowing down the immune system's attack in newly diagnosed type 1 diabetes patients so that the remaining beta-cells can survive and keep making some of the insulin needed by the body.

- The MMF/DZB Study will see whether a combination of two medicines can stop the immune system from destroying beta cells in new onset type 1 diabetes patients (within 3 months of diagnosis). ■

Other Current Clinical Trials

- The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the NIH, has set up an online list of type 1 diabetes clinical trials that users can use to search by location or by eligibility (such as age), visit www.t1diabetes.nih.gov/T1D_CTCR/studies.shtml.
- The Immune Tolerance Network (ITN) conducts clinical trials and tolerance assay studies in the following disease areas: Transplantation (Islet, Kidney, Liver), Autoimmune Diseases, and Allergy & Asthma. Information is provided on current clinical trials in new-onset type 1 diabetes, visit www.immunetolerance.org/trials/list.html.
- ClinicalTrials.gov also lists NIH-sponsored trials that have been scientifically reviewed through NIH mechanisms and approved by government council, visit www.clinicaltrials.gov.
- Children with Diabetes lists a number of trials actively seeking participants, visit <http://www.childrenwithdiabetes.com/studies/>.
- CenterWatch also includes geographic listings of current trials regarding type 1 diabetes, visit www.centerwatch.com/patient/studies/cat602.html.

Type 1 Diabetes in Children

Type 1 diabetes has an acute onset, with children and adolescents usually able to pinpoint when symptoms began. Onset can occur at any age, but it most often occurs in children and young adults.

As the pancreas can no longer produce insulin, people with type 1 diabetes require daily injections of insulin for life. Children with type 1 diabetes are at risk for long-term complications such as damage to the cardiovascular system, kidneys, eyes, nerves, blood vessels, gums, and teeth.

Type 1 diabetes accounts for 5% to 10% of all diagnosed cases of diabetes, but is the leading cause of diabetes in children. A diabetes management plan for young people includes insulin therapy, self-monitoring of blood glucose, healthy eating, and physical activity. The plan is designed to ensure proper growth and prevention of hypoglycemia. New management strategies are helping children with type 1 diabetes live long and healthy lives.

Symptoms. The symptoms of type 1 diabetes usually develop over a short period of time. They include:

- **Increased thirst and urination**
- **Constant hunger**
- **Weight loss**
- **Blurred vision.**

If not diagnosed and treated with insulin, the child with type 1 diabetes can lapse into diabetic ketoacidosis (DKA). Often, children will present with vomiting, a sign of DKA, and mistakenly be diagnosed as having gastroenteritis. New-onset diabetes can be differentiated from a GI infection by the frequent urination that accompanies continued vomiting, as opposed to decreased urination due to dehydration if the vomiting is caused by a GI infection.

Risk Factors. A combination of genetic and environmental factors put people at increased risk for type 1 diabetes.

Comorbidities. Autoimmune diseases such as celiac disease and autoimmune thyroiditis are associated with type 1 diabetes.

Source: http://ndep.nih.gov/diabetes/youth/youth_FS.htm#Type1