

Intervention Studies in Newly Diagnosed Diabetes

- The goal of these research studies is to preserve insulin secretion in people newly diagnosed with type 1 diabetes.
- Eligible participants will be randomly (like the flip of a coin) put into either an experimental treatment group or a control group. The experimental group will receive the new treatment and the control group will receive a "pretend" treatment. Differences between the two groups will help researchers know if the experimental treatment is successful.
- Ongoing intervention studies will be available at specific TrialNet sites located at medical institutions in the United States and Canada.

WHO CAN PARTICIPATE IN INTERVENTION STUDIES?

You may be eligible to participate in a diabetes intervention study if you are:

- Between the ages of 12 to 35 years of age
- Newly diagnosed with type 1 diabetes within the last 3 months

WHY SHOULD YOU PARTICIPATE IN AN INTERVENTION STUDY?

- You will be a part of a research study to learn if it is possible to save remaining insulin production after a diagnosis of diabetes.
- If the intervention is successful, your diabetes may be easier to manage, possibly reducing your risks of abnormal blood sugar levels and long-term complications.

WHAT IS TYPE 1 DIABETES?

Type 1 diabetes is a life-long disease that can affect both children and adults. It occurs when the body attacks and destroys the cells in the pancreas that make insulin. The body needs insulin, which is a hormone required to use food for energy.

WHAT IS TYPE 1 DIABETES TRIALNET?

Type 1 Diabetes TrialNet is a network of 18 clinical centers dedicated to conducting diabetes prevention research and studying intervention therapies for children and adults with newly diagnosed diabetes. TrialNet centers work in cooperation with screening sites located throughout the United States, Canada, Europe and Australia/New Zealand. TrialNet researchers are experts in both diabetes and the body's immune system. They share common scientific goals related to the study, treatment, and prevention of type 1 diabetes.

TrialNet is conducting three types of research:

- **Natural History Studies:** These studies will enable us to learn more about risk factors associated with the development of type 1 diabetes.
- **Diabetes Prevention Studies:** These studies will test therapies that may delay or prevent the onset of type 1 diabetes.
- **Diabetes Intervention Studies:** These studies will test therapies to preserve insulin secretion in people recently diagnosed with type 1 diabetes.

TO GET A REFERRAL TO A TRIALNET SITE, CALL TOLL FREE 1-800-HALT-DM1 (1-800-425-8361)

You will then receive:

- A phone evaluation to find out if you might be eligible for any current TrialNet studies
- A referral to the closest clinical site in your area
- An information packet for the type of research that is of interest to you

If you wish to be tested for diabetes risk, but do not live near a TrialNet site, we will refer you to Clinical Center staff who will explain the screening process and provide you with a test kit to have your blood test performed locally by your own physician.

You may also learn about TrialNet at www.diabetestrialnet.org

Information will be maintained in a confidential manner.

Type 1 Diabetes TrialNet is sponsored by the following organizations:



National Institute of Diabetes & Digestive & Kidney Diseases
NATIONAL INSTITUTES OF HEALTH



National Institute of Allergy and Infectious Diseases
NATIONAL INSTITUTES OF HEALTH



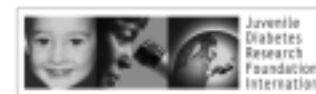
National Institute of Child Health and Human Development (NICHD)



National Center for Research Resources



DEPARTMENT OF HEALTH & HUMAN SERVICES - USA



Juvenile Diabetes Research Foundation International
dedicated to finding a cure

American Diabetes Association®
Cure • Care • Commitment®

DO YOU WANT TO LEARN MORE ABOUT Type 1 Diabetes RESEARCH STUDIES?



Type 1
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Initial Screening for Risk of Developing Diabetes

TrialNet is screening relatives of people with type 1 diabetes to find out if these family members are at risk for developing diabetes. *[IF YOU ALREADY HAVE DIABETES, SEE THE SECTION ABOUT INTERVENTION STUDIES.]*

- Screening involves a simple blood test for the presence of diabetes-related autoantibodies that may appear years before type 1 diabetes develops.
- **First-degree blood relatives** (siblings, children or parents) who are 1 to 45 years of age as well as **second-degree blood relatives** (cousins, uncles, aunts, nieces, nephews, grandparents or half-siblings) who are 1 to 20 years of age may be screened to determine their risk of developing type 1 diabetes.

Note: A relative diagnosed before the age of 40 AND started on insulin within the first year of diagnosis probably has type 1 diabetes.

- Relatives of people with type 1 diabetes have about a 3-4 percent chance of testing positive for autoantibodies associated with diabetes.
- There is no cost for the test.

HOW WILL YOU BENEFIT FROM SCREENING AND FURTHER RISK ASSESSMENT?

- If you learn you are at risk for developing type 1 diabetes, additional tests will be offered to estimate your chances of developing type 1 diabetes.
- If you qualify, you may have an opportunity

to be enrolled in either a **Natural History or Prevention Study**.

- All research volunteers will be closely monitored for early detection of type 1 diabetes.
- Early detection of type 1 diabetes may improve your blood sugar control and reduce your chances of developing complications.
- You will be part of a research program that may help other people at risk for type 1 diabetes.

NATURAL HISTORY STUDIES

- Natural history studies are being done to learn more about what causes type 1 diabetes and to better define predictors of the disease process.
- These studies provide close monitoring to individuals at risk for developing type 1 diabetes.

- Individuals who qualify may be offered an opportunity to participate in a prevention study.

DIABETES PREVENTION STUDIES

- Diabetes prevention studies are being planned to determine whether new therapies can delay, or prevent, the onset of type 1 diabetes in "at-risk" individuals.
- If you are enrolled in a prevention trial, your development of diabetes may be delayed, or prevented, if the therapy being tested is successful. *(Note: Eligibility criteria will vary for different diabetes prevention studies.)*

A Network of Clinical Sites Throughout the United States, Canada, Europe and Australia/New Zealand is Connected with the Following Clinical Centers:

California

Childrens Hospital Los Angeles
Los Angeles, CA
(888) 835-3761

Stanford University Medical Center
Stanford, CA
(877) 232-5182

University of California,
San Francisco
San Francisco, CA
(415) 514-3730

Colorado

Barbara Davis Center for
Childhood Diabetes
University of Colorado
Denver, CO
(800) 572-3992

Florida

University of Florida
Gainesville, FL
(800) 749-7424, dial 1,
Ext. 334-0857

University of Miami School
of Medicine
Miami, FL
(305) 243-3781

Indiana

Riley Hospital for Children
Indiana University
Indianapolis, IN
(866) 230-8486

Massachusetts

Joslin Diabetes Center
Children's Hospital Boston
Boston, MA
(800) 242-5836

Minnesota

University of Minnesota
Minneapolis, MN
(800) 688-5252, Ext. 58944

New York

Naomi Berrie Diabetes Center
Columbia University
New York, NY
(212) 851-5425

Pennsylvania

Children's Hospital of Pittsburgh
of UPMC
Pittsburgh, PA
(412) 692-5210

Texas

University of Texas Southwestern
Medical Center at Dallas
Dallas, TX
(214) 648-4844

Washington

Benaroya Research Institute
at Virginia Mason
Seattle, WA
(800) 888-4187

Canada

The Hospital for Sick Children
Toronto, Ontario
(866) 699-1899

Australia/New Zealand

Walter and Eliza Hall Institute
of Medical Research
Parkville, Victoria
+61-3-93452555

Finland

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Department of Pediatrics
Turku, Finland
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Italy

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