

TEDDY - The Environmental Determinants of Diabetes in the Young

This study is currently recruiting participants.

Verified by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), May 2009

First Received: January 17, 2006 Last Updated: May 20, 2009 [History of Changes](#)

Sponsors and Collaborators:	<u>National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)</u> <u>National Institute of Allergy and Infectious Diseases (NIAID)</u> <u>Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)</u> <u>National Institute of Environmental Health Sciences (NIEHS)</u> Juvenile Diabetes Research Foundation <u>Centers for Disease Control and Prevention</u>
Information provided by:	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

ClinicalTrials.gov Identifier:	NCT00279318
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▶ Purpose

The long-term goal of the TEDDY study is the identification of infectious agents, dietary factors, or other environmental agents, including psychosocial factors which trigger T1DM in genetically susceptible individuals or which protect against the disease. Identification of such factors will lead to a better understanding of disease pathogenesis and result in new strategies to prevent, delay or reverse T1DM.

<u>Condition</u>
Type 1 Diabetes Mellitus

[MedlinePlus](#) related topics: [Diabetes](#) [Diabetes Type 1](#) [Diets](#)
[U.S. FDA Resources](#)

Study Type: Observational

Study Design: Prospective

Official Title: Consortium for Identification of Environmental Triggers of **Type 1 Diabetes**

Further study details as provided by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK):

Biospecimen Retention: Samples With DNA

Biospecimen Description:

Serum, plasma, stool, saliva, nail clippings, water

Estimated Enrollment: 7801

Study Start Date: September 2004

Estimated Study Completion Date: September 2023

Detailed Description:

Epidemiologic patterns suggest that viruses, nutrition, toxic agents or socioeconomic psychosocial factors may contribute to the etiology alone or in combination. Elucidation is confounded by the long interval between exposure and onset of clinical disease, as well as the interaction of multiple genes and/or insults, which appear to interact in a complex manner. Numerous studies have investigated environmental influences but have yielded conflicting results. This may be in part due to the failure to account for genetic susceptibility, begin observation at early ages or in utero, and/or monitor subjects long term and frequently.

Hypotheses:

1. Initiation of persistent beta-cell autoimmunity and progression from beta-cell autoimmunity to diabetes is increased with:
 1. Exposure to a trigger factor during pregnancy, such as infections, preeclampsia, blood incompatibility, or birth weight.
 2. Differences in the timing of the introduction and/or the type of dietary constituents that include exposure to cereals or gluten, exposure to cow's milk during infancy and/or childhood, and short duration of breast-feeding;
 3. Lower intake of serum 25 hydroxyvitamin D in early infancy, vitamin E, anti-oxidants (e.g., carotenoids, ascorbic acid, selenium, or omega-3 fatty acids);
 4. Higher frequency of specific (e.g., enterovirus, rotavirus, or bacterial) infections, or non-specific childhood infections including those that exhibit molecular mimicry;
 5. Increased exposure to routine childhood immunizations and their timing;
 6. Environmental factors that may be contained in drinking water (e.g., low concentrations of zinc or high concentrations of nitrates, or lower pH levels);
 7. Exposure to household pets, and various allergies;
 8. Excessive weight gain;
 9. Increased psychological stress.
2. The risk of persistent beta-cell autoimmunity is lower in children from the general population than in offspring or siblings of T1DM patients when stratifying for the HLA DR-DQ genotype and exposure to environmental triggers.
3. The interaction of HLA DR-DQ genotype with exposure to dietary or infectious factors leads to increased incidence of beta-cell autoimmunity and T1DM.
4. We expect that in some families study participation will be associated with affective (anxiety, depression) and behavioral responses (e.g. actions to prevent possible T1DM).

Eligibility

Ages Eligible for Study: up to 4 Months

Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes
Sampling Method: Non-Probability Sample

Study Population

Children up to 4 months of age with specified HLA are enrolled and followed longitudinally

Criteria

Inclusion Criteria:

- Newborns with high risk HLA in the general population or having a first-degree relative affected with T1DM
- Newborns are less than 4 months of age

Exclusion Criteria:

- Have an illness or birth defect that precludes long-term follow-up or involves use of treatment that may alter the natural history of diabetes (e.g. steroids or insulin)
- Refuses to have blood and stool samples stored at the NIDDK Repository

▶ Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00279318

Locations

United States, Colorado

University of Colorado Health Sciences Center
Denver, Colorado, United States, 80262
Contact: Judith Baxter, MA 303-315-6857
judy.baxter@uchsc.edu
Principal Investigator: Marian Rewers, MD, PhD

Recruiting

United States, Florida

Medical College of Georgia
Gainesville, Florida, United States, 32608
Contact: Angie Choate 352-334-0843
choatal@pediatrics.ufl.edu
Principal Investigator: Jin-Xiong She, PhD

Recruiting

United States, Georgia

Medical College of Georgia
Augusta, Georgia, United States, 30912
Contact: Diane I Hopkins, MS, CCRC 706-721-4161
dhopkins@mcg.edu

Recruiting

Principal Investigator: Jin-Xiong She, PhD

Medical College of Georgia

Atlanta, Georgia, United States, 30342

Contact: Leigh Steed, RN,CDE,CCRC

404-252-0844

lsteed@mail.mcg.edu

Contact: Kate Silvis, MS, RD, LD

404-252-0844

ksilvis@mail.mcg.edu

Principal Investigator: Jin-Xiong She, PhD

Recruiting

United States, New York

Naomi Berrie **Diabetes** Center, Columbia University Medical Center (this site is only screening babies whose mother, father or full sibling have **type 1 diabetes**)

Recruiting

New York, New York, United States, 10032

Contact: Diana Arnold

212-851-5466

dea2101@columbia.edu

Sub-Investigator: Robin Goland, MD

United States, Pennsylvania

Children's Hospital of Pittsburgh of UPMC (this site is only screening babies whose mother, father or full sibling have **type 1 diabetes**)

Recruiting

Pittsburgh, Pennsylvania, United States, 15213

Contact: Peggy Franciscus

412-692-5250

margaret.franciscus@chp.edu

Sub-Investigator: Dorothy Becker, MD

United States, Washington

Pacific Northwest Research Institute

Recruiting

Seattle, Washington, United States, 98122

Contact: William Hagopian, MD, PhD

206-726-1200

wah@u.washington.edu

Principal Investigator: William Hagopian, MD, PhD

Finland

Turku University Central Hospital

Recruiting

Turku, Finland, 20520

Contact: Olli Simell, MD, PhD

358-2-313 2466

olli.simell@utu.fi

Contact: Tuula Simell, MPH, PhD

358-2-313 3427

tuula.simell@utu.fi

Principal Investigator: Olli Simell, MD, PhD

Germany

Diabetes Research Institute

Recruiting

Munich, Germany, 80804

Contact: Anette G. Ziegler, MD 0049 / 89 / 30 79 31-21
anziegler@lrz.uni-muenchen.de

Contact: Christiane Winkler 0049 / 89/ 30 79 31-14
christiane.winkler@lrz.uni-muenchen.de

Principal Investigator: Anette G. Ziegler, MD

Sweden

University of Lund

Malmö, Sweden, 20502

Contact: Barbro Lernmark, PhD 46 40 332390
barbro.lernmark@med.lu.se

Contact: Ake Lernmark, MD, PhD 46 40 336963
ake.lernmark@med.lu.se

Principal Investigator: Ake Lernmark, MD, PhD

Recruiting

Sponsors and Collaborators

[National Institute of Diabetes and Digestive and Kidney Diseases \(NIDDK\)](#)

[National Institute of Allergy and Infectious Diseases \(NIAID\)](#)

[Eunice Kennedy Shriver National Institute of Child Health and Human Development \(NICHD\)](#)

[National Institute of Environmental Health Sciences \(NIEHS\)](#)

[Juvenile Diabetes Research Foundation](#)

[Centers for Disease Control and Prevention](#)

Investigators

Principal Investigator:	Jeffrey P. Krischer, PhD	University of South Florida
Principal Investigator:	Marian J. Rewers, MD, PhD	University of Colorado Health Science Center
Principal Investigator:	William A. Hagopian, MD, PhD	Pacific Northwest Research Institute
Principal Investigator:	Ake Lernmark, MD, PhD	University of Washington & University of Lund
Principal Investigator:	Olli G. Simell, MD, PhD	University of Turku
Principal Investigator:	Jin-Xiong She, PhD	Medical College of Georgia
Principal Investigator:	Anette G. Ziegler, MD	University of Miami
Principal Investigator:	Beena Akolkar, PhD	National Institutes of Diabetes and Digestive Kidney Diseases

▶ More Information

Additional Information:

[TEDDY Study Public site](#) 

No publications provided

Responsible Party: University of South Florida (Dr. Jeffrey Krischer)
Study ID Numbers: DK63790, 5U01DK063790-04
Study First Received: January 17, 2006
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Health Authority: United States: Federal Government; United States: Institutional Review Board

Keywords provided by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK):

Environment	Infectious Agents
Exposures	Bacterial
Diet	Viral
Toxins	Immunizations
Psychosocial	Autoantibody

Study placed in the following topic categories:

Autoimmune Diseases	Endocrine System Diseases
Metabolic Diseases	Diabetes Mellitus Type 1
Autoantibodies	Endocrinopathy
Diabetes Mellitus, Type 1	Glucose Metabolism Disorders
Diabetes Mellitus	Metabolic Disorder

Additional relevant MeSH terms:

Autoimmune Diseases	Diabetes Mellitus
Metabolic Diseases	Glucose Metabolism Disorders
Immune System Diseases	Diabetes Mellitus, Type 1
Endocrine System Diseases	

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