TrialNet Natural History Study of the Development of Type I Diabetes

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Synopsis:

The overall objective of this study is to perform baseline and repeat assessments over time of the metabolic and immunologic status of individuals at risk for T1D in order:

a) To characterize their risk for developing TID,
b) To describe the pathogenetic evolution of TID, and
c) To increase the understanding of the pathogenetic factors involved in the development of TID.

Within this overall objective, the specific objectives are:

1. To determine the risk for the occurrence of TID according to oral glucose tolerance tests (OGTT), C-peptide levels, biochemical autoantibodies (anti-GAD65, anti-ICA512 and IAA), islet cell autoantibodies (ICA), markers of cell-mediated immunity, and HLA genetic markers that are associated with risk for TID.
2. To examine the accuracy of TrialNet risk assessment procedures for predicting future TID.
3. To determine the prevalence of impaired glucose tolerance and ICA positivity in individuals with at least one positive biochemical autoantibody test.
4. To characterize the progression of immunologic abnormalities in the development of TID by serially studying biochemical autoantibodies, ICA, and markers of cell-mediated immunity.
5. To characterize the progression of metabolic decompensation in the development of TID by serially studying insulin, C-peptide and glucose levels, and to identify immunologic and other factors associated with this decompensation.
6. To determine the incidence of severe acute metabolic decompensation as the initial clinical presentation in individuals who have been identified as being at increased risk for TID.
7. To identify individuals who qualify for TrialNet prevention trials for TID.
8. To accrue additional information about immunologic and metabolic factors related to the pathogenesis of TID by analyzing stored blood samples. The Immune Tolerance Network will function as a core laboratory for TrialNet for the development of specialized immunologic procedures.
9. To accrue additional information about genetic markers associated with risk for the development of TID by analyzing stored blood samples.
10. For those who participated in the DPT-1 study, to examine associations of characteristics (e.g. demographics, immunologic, metabolic, etc.) assessed during the DPT-1 study with characteristics and outcomes assessed in TrialNet.