Oral Insulin for Prevention of Diabetes in Relatives at Risk for Type 1 Diabetes Mellitus

IRB# 2007-14
Principal Investigator: Jennifer Olson, MD

Synopsis:

The purpose of this trial is to evaluate whether oral administration of recombinant human insulin will prevent or delay the development of T1DM in non-diabetic relatives of patients with type 1 diabetes who are positive for insulin autoantibodies but who do not have a metabolic defect (primary analysis strata).

The primary outcome is the time elapsed from random treatment assignment to the development of diabetes among those enrolled in the primary analysis cohort. Secondary analyses consist of 3 different cohorts with subjects who are positive for either insulin autoimmunity and/or have other autoantibodies, and are with or without a metabolic defect.

Criteria for diabetes onset are, as defined by the American Diabetes Association, based on glucose testing or the presence of unequivocal hyperglycemia with acute metabolic decompensation.

The primary statistical hypothesis to be assessed in the study is the cumulative incidence of diabetes onset over time since randomization within each group in the primary analysis cohort.