



TYPE 1 DIABETES: 8 - 17 YEARS OF AGE WITHIN 30 DAYS OF DIABETES DIAGNOSIS

DRUG NAME: TEPLIZUMAB

Study Name: A Phase 3, Randomized, Double-Blind, Multinational, Placebo-Controlled Study to Evaluate Efficacy and Safety of Teplizumab (PRV-031), a Humanized, FcR Non-Binding, anti-CD3 Monoclonal Antibody, in Children and Adolescents with Newly Diagnosed Type 1 Diabetes (T1D)

Study Sponsors: Provention Bio, LLC

Principal Investigator: Stephen E. Gitelman, MD

Who can sign up for this study? Volunteers must be 8-17 years of age and have had diabetes for no more than 42 days

In addition, participants cannot have any of the following conditions:

- No active infection
- No history of liver disease
- No history of cancer
- No pregnancy or breastfeeding
- No concurrent autoimmune disease
- No concurrent use of steroids
- No active infection
- No vaccinations within the past 4 weeks.

What is this study about? UCSF Diabetes Program is conducting a study to assess the safety, tolerability, and effectiveness of teplizumab, an investigational drug, in recently diagnosed T1DM individuals.

What will happen in this study? All volunteers will undergo a screening visit where they will be asked questions about their medical history, undergo a physical exam, and provide blood and urine for tests. Volunteers who qualify and are enrolled in the study will receive a single 12-day study treatment of teplizumab / placebo and then another 12-day study treatment of teplizumab / placebo 6 months later. There is a 2:1 chance of being randomized into the active study treatment group. You cannot choose which group you will be in.

All volunteers will be monitored for approximately 1 year to assess their overall health and to perform laboratory testing to determine the effects of the study treatment. This will require several visits to UCSF for laboratory testing during this period.

How long will this study last? Each volunteer will be followed for approximately 2½ years.

Reimbursement: You will not be charged for any of the study treatments and may be eligible for reimbursement for your time.

For more information please contact: UCSF Pediatric Endocrinology Type 1 Diabetes Clinical Research Team, phone: 844-813-8273 (toll-free) or email clinicalresearch@diabetes.ucsf.edu