Referring Information

and Physicians' Study Reference

START
STUDY OF THYMOGLOBULIN TO ARREST TYPE 1 DIABETES

www.type1diabetestrial.org

A multicenter, placebo-controlled, randomized, blinded phase II trial of Thymoglobulin® for the treatment of new onset type 1 diabetes

STUDY DESIGN

66 subjects randomized 2:1 (44 in treatment group, 22 in placebo group) over 8 clinical sites in the US. The study lasts 2 years, with optional follow-up to 5 years in some cases.

PROTOCOL SUMMARY

Subjects must be randomized within 3 months of T1DM diagnosis and attend a screening visit that includes a mixed meal tolerance test (MMTT).

Eligible subjects will be randomized and hospitalized for 5-8 days while receiving 4 daily infusions of Thymoglobulin or placebo.

After treatment, participants will be asked to attend 8 follow-up appointments in the first year and 4 during the second year.

Working with primary care physicians and the study team, all participants will participate in an intensive diabetes management program

All participants will receive a blood glucose monitor and testing supplies for the duration of the study.

STUDY MEDICATION

Thymoglobulin (Genzyme) is a polyclonal rabbit anti-thymocyte globulin (ATG) currently FDA-approved for the treatment and prevention of organ transplant rejection. ATGs induce immunosuppression by T cell clearance and modulation of T cell activation, homing and cytotoxic activities.

In animal models of new onset T1DM, ATGs have been shown to induce lasting remission when administered in a short course of treatment. In a previous human study, 4/5 ATG-treated subjects exhibited lower HbA1C on <0.2 U/kg/day of insulin for 100+ days after treatment; 2 subjects required no exogenous insulin for more than 8 months. Interim data from a blinded, controlled European study showed positive clinical and laboratory results. Adverse events have included fever, phlebitis at the infusion site and fever with arthralgia 9-11 days after the first dose, consistent with serum sickness.

ATG has also been used to treat other autoimmune conditions, either alone or in combination with other agents, including MS, rheumatoid arthritis, Wegner's granulomatosis, SLE, aplastic anemia, scleroderma and myelodysplastic disorders.

KEY ELIGIBILITY CRITERIA

- 12 to 35 years of age;
- Diagnosis of type 1 diabetes (according to ADA criteria) within 100 days of study entry;
- Positive for at least one islet cell autoantibody (glutamate decarboxylase; insulin, if obtained within 10 days of the onset of insulin therapy; ICA 512 and/or ICA);
- No active infection with HIV hepatitis, tuberculosis, EBV, CMV, or toxoplasmosis
- No prior history of significant cardiac disease
- Have not used oral, inhaled or intranasal glucocorticoids in the 28 days prior to study entry
- Have not used metformin, sulfonylureas, thiazolidinediones, or amylin

REFERRALS

SF Bay Area	(415) 353-9084
San Diego	(858) 966-8940
Los Angeles	(323) 361-5961
Denver	(303) 724-6768
Kansas City	(816) 234-3975
Minneapolis	(612) 624-5958
Philadelphia	(215) 590-5007

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