

The Protégé Study - Clinical Trial of MGA031 in Children and Adults With Recent-Onset Type 1 Diabetes Mellitus

This study is currently recruiting participants.

Verified by MacroGenics, April 2009

First Received: October 7, 2006 Last Updated: May 12, 2009 [History of Changes](#)

Sponsored by:	MacroGenics
Information provided by:	MacroGenics
ClinicalTrials.gov Identifier:	NCT00385697

▶ Purpose

The primary purpose of this protocol is to assess the efficacy, tolerability, and safety of MGA031 when administered according to 3 different MGA031 dosing regimens in children and adults with recent-onset (diagnosis within past 12 weeks) **type 1 diabetes mellitus**. All regimens will be administered as an addition to insulin and other standard of care treatments. Efficacy will be defined primarily by the capacity of MGA031 to markedly reduce typical insulin requirements while maintaining relatively normal blood sugar levels.

Other studies involving the study drug use the name hOKT3γ1 (Ala-Ala). MGA031, a humanized monoclonal antibody, is the name used for hOKT3γ1 (Ala-Ala) that is produced by MacroGenics, Inc. The United States Adopted Name (USAN) for MGA031 is teplizumab.

<u>Condition</u>	<u>Intervention</u>	<u>Phase</u>
Type 1 Diabetes Mellitus	Drug: Teplizumab Other: Placebo	Phase II Phase III

[MedlinePlus](#) related topics: [Diabetes](#) [Diabetes Type 1](#)

[U.S. FDA Resources](#)

Study Interventional
Type:

Study Treatment, Randomized, Double Blind (Subject, Caregiver), Active

Design: Control, Parallel Assignment, Efficacy Study

Official Title: A Phase 2/3, Randomized, Double-Blind, Multicenter, Multinational, 4-Arm, Controlled, Dose-Ranging Study to Evaluate Efficacy and Safety of MGA031, a Humanized, FcR Non-Binding, Anti-CD3 Monoclonal Antibody, in Children and Adults With Recent-Onset **Type 1 Diabetes Mellitus**

Further study details as provided by MacroGenics:

Primary Outcome Measures:

- Successful versus unsuccessful clinical responses. A successful response requires that both components of a composite endpoint are met. The composite endpoint includes both the subject's total daily insulin usage and his/her HbA1c levels. [Time Frame: at 12 months]
[Designated as safety issue: Yes]

Secondary Outcome Measures:

- Successful versus unsuccessful clinical responses. A successful response requires that both components of a composite endpoint are met. The composite endpoint includes both the subject's total daily insulin usage and his/her HbA1c levels. [Time Frame: at 24 months]
[Designated as safety issue: Yes]
- C-peptide secretory responses, as defined by the total area under the curve of the C-peptide response to a mixed meal [Time Frame: at 24 months]
[Designated as safety issue: Yes]

Estimated Enrollment: 530

Study Start Date: October 2006

Estimated Study Completion Date: March 2011

Estimated Primary Completion Date: March 2010 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
1: Experimental	Drug: Teplizumab IV dosing daily for 14 days times 2 courses
2: Experimental	Drug: Teplizumab

	IV dosing daily for 14 days times 2 courses
3: Experimental	Drug: Teplizumab IV dosing daily for 14 days times 2 courses
4: Placebo Comparator	Other: Placebo IV dosing daily for 14 days times 2 courses

Detailed Description:

The Protégé Study - A Multinational Clinical Trial of MGA031 for Preserving the Capability to Produce Insulin, Reducing Insulin Usage and Improving Blood Sugar Levels in Children and Adults With Recent-Onset Type 1 Diabetes Mellitus

► Eligibility

Ages Eligible for Study: 8 Years to 35 Years

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

Subjects must meet all of the following criteria:

1. Enrollment (Segment #1) or randomization (Segment #2) on Study Day 0 within 12 weeks of first visit to any physician for symptoms or signs of diabetes. Study Day 0 is the first day of study drug dosing.
2. Diagnosis of type 1 diabetes mellitus, according to the American Diabetes Association (ADA) criteria
3. Requirement for injected insulin therapy
4. Have a detectable fasting or stimulated C-peptide level (above the lower limit of detection of the assay)
5. One positive result on testing for any of the following antibodies:
 1. islet-cell autoantibodies (ICA512/IA-2),
 2. glutamic acid decarboxylase autoantibodies, or
 3. insulin autoantibodies (if present during first 2 weeks, but not beyond 2 weeks, of insulin treatment)
6. Male or female
7. Subject must be in one of the following age groups:
 - Age 18-35 years
 - Age 12-17 years pending approval by Data Monitoring Committee
 - Age 8-11 years pending approval by Data Monitoring Committee
8. Body weight \geq 36 kg

Exclusion Criteria:

Subjects must have none of the following:

1. Prior administration of a monoclonal antibody -- within the 1 year before enrollment or randomization at Study Day 0 -- that could potentially prevent or confound a therapeutic response to MGA031
2. Participation in any type of therapeutic drug or vaccine clinical trial within the 12 weeks before enrollment or randomization
3. Any medical condition that, in the opinion of the investigator, would interfere with safe completion of the trial
4. Pregnant or lactating females
5. Prior murine OKT®3 treatment at any time before enrollment or randomization
6. Current or planned therapy with exenatide or any other agents that stimulate pancreatic beta cell regeneration or insulin secretion
7. Current or planned therapy with inhaled insulin
8. Uncompensated heart failure, fluid overload, myocardial infarction or evidence of ischemic heart disease, or other serious cardiac disease within the 12 weeks before enrollment or randomization
9. History of epilepsy, cancer, cystic fibrosis, sickle cell anemia, neuropathy, peripheral vascular disease or cerebrovascular disease
10. Newly diagnosed hypothyroidism (not currently being treated but which, in the opinion of the investigator, should be treated) or active Graves' disease
11. Eczema, asthma or severe atopic disease requiring treatment within the 12 weeks before enrollment or randomization
12. Evidence of active infection, such as fever ≥ 38.0 degrees Celsius (100.5 degrees Fahrenheit)
13. Known or suspected infection with human immunodeficiency virus (HIV)
14. Evidence of active hepatitis B (HBV) or hepatitis C virus (HCV)
15. Evidence of active or latent tuberculosis
16. Vaccination with a live virus within the 12 weeks before enrollment or randomization or planned live virus vaccination continuing through week 52 of the study. Vaccination with an antigen or killed organism must not be given within 12 weeks before or planned within 8 weeks after each dosing cycle.
17. Any infectious mononucleosis-like illness within the 6 months before enrollment or randomization
18. Serologic and clinical evidence of acute infection with Epstein-Barr virus (EBV)
19. Serologic evidence of acute infection with cytomegalovirus (CMV)

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00385697

Contacts

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 [Hide Study Locations](#)

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United Kingdom, Cambridgeshire

Addenbrookes Hospital Cambridge, Cambridgeshire, United Kingdom, CB20QQ	Active, not recruiting
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United Kingdom, Devon

Royal Devon and Exeter Hospital Exeter, Devon, United Kingdom, EX25DW	Active, not recruiting
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Sponsors and Collaborators

MacroGenics

 **More Information**