

Just diagnosed with **type 1 diabetes**?

Take action.

We're looking for people who have been recently diagnosed with type 1 diabetes to participate in a clinical research study which may help slow the effects of type 1 diabetes.

Why is the study being conducted?

The Protégé study will further evaluate the safety of the investigational drug, teplizumab, and will test whether it will reduce or prevent the autoimmune attack that damages insulin-producing beta cells in the pancreas. If teplizumab works, people with type 1 diabetes may need less injected insulin. Also, blood glucose levels may be easier to control if the remaining beta cells are preserved.

Who can participate in the study?

If you meet the eligibility requirements, you will join up to 530 volunteers who will participate in this study at approximately 85 medical facilities in 10 countries.

To be in the Protégé study, you must:

- Be 8 to 35 years of age
- Have had your first visit to a doctor for symptoms of type 1 diabetes and received that diagnosis within 12 weeks of starting the study
- Weigh at least 36 kg (79 lbs)
- Not be using any other experimental treatment during the time you are in the study
- Not have received treatment with a monoclonal antibody within 1 year before joining the study
- Not currently be using or planning to use inhaled insulin
- Not have received a vaccination with a live virus within 12 weeks before joining the study

How may participants benefit?

People with type 1 diabetes are prone to a number of complications from the disease. These include heart disease, kidney disease, high blood pressure, and blindness. You or your child may or may not directly benefit from this study. You will need to weigh the possible risks of the study medication against the possible benefits of participating in this study. What we learn from this study will be added to the

research knowledge base and may help others at risk for type 1 diabetes.

Those who join the study will receive, at no cost:

- Close monitoring of their disease
- Direct access to physicians or nurses to answer questions and concerns
- Physical examinations
- Blood work
- Study medication

What will study participants be asked to do?

As a study participant, you (or your child) will be asked to:

- Confirm that you have had your first visit to a doctor for symptoms of type 1 diabetes and received that diagnosis within 12 weeks of starting the study
- Give consent for the study
- Have urine and blood tests to see if you meet the criteria for the study
- Receive daily IV infusions of the study drug for up to 14 consecutive days at an outpatient facility. This will occur twice: at the very beginning of the study and then again 6 months later.
- Attend 14 additional study visits during the two-year study period

For more information or to find out if you may be eligible, please contact:

Dr. Celeste Hart

MPRA

Janice Johnson, CRC

850-878-1602

or visit www.ProtegeDiabetes.org

Protégé

Research to **Protect Beta Cells**

Just diagnosed with **type 1 diabetes**?

Take action.

Learn more about the Protégé study.

People diagnosed with type 1 diabetes lose their ability to produce insulin, which helps control sugar levels in the blood. When people are first diagnosed with type 1 diabetes, their bodies still make some insulin, but not much. Insulin is produced by beta cells in the pancreas.

When people are diagnosed with type 1 diabetes, approximately 90 percent of their beta cells have stopped producing insulin. Soon after a patient's diagnosis, the remaining beta cells will stop making insulin. As a result, people with type 1 diabetes must take injected insulin to survive.

Researchers with the Protégé study are testing an investigational medication – teplizumab – to further evaluate its safety and see if it helps people with newly diagnosed type 1 diabetes. They hope it will protect the remaining beta cells of the pancreas before they have lost their ability to make insulin. If teplizumab works, a person may need less injected insulin and their blood glucose levels may be easier to control.

But the window of opportunity for this treatment is short. You must enroll in the study as soon as possible after your first visit to a doctor for symptoms of diabetes.

The Protégé study will enroll approximately 530 patients with type 1 diabetes. Study participants must:

- Be 8 to 35 years old
- Weigh at least 79 pounds (36 kilograms)
- Have blood tests and other laboratory work to see if the study meets their needs

If you think you may want to join this study, call us as soon as possible. It is important that you **call within 9 weeks** of your first visit to a doctor with symptoms of type 1 diabetes. The sooner, the better!

To learn more about the Protégé study, please contact:

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