



Natural History Study of the Development of Type 1 Diabetes

A Pathway to Prevention

Welcome to Type 1 Diabetes TrialNet and the Natural History Study. This study is helping us learn more about how type 1 diabetes develops and ways to delay and prevent it.

If we find that you are at increased risk for type 1 diabetes, you may be able to take part in a prevention study. That's why we think of the Natural History Study as a pathway to prevention.

What is type 1 diabetes?

Type 1 diabetes is a life-long disease that occurs in both children and adults. It develops when the body attacks and destroys insulin-producing cells in the pancreas.

The immune attack that leads to diabetes goes on for years before the person has symptoms. A blood test can tell us if there are signs that the attack has begun.

Can I be screened for the Natural History Study?

TrialNet screens relatives of people with type 1 diabetes. They have about 15 times greater risk for developing the disease than people with no family history.

We can screen you for the Natural History Study if you are:

- 1 to 45 years old and have a brother, sister, child, or parent with type 1 diabetes, OR
- 1 to 20 years old and have a cousin, aunt, uncle, niece, nephew, half-brother, half-sister, or grandparent with type 1 diabetes.

(Your relative probably has type 1 diabetes if he or she was diagnosed before age 40 and needed insulin injections within a year.)

How is the test done?

A small sample of blood is drawn from your arm. The blood is tested for autoantibodies. Autoantibodies are markers that show that the immune system is turned on.

- You can have the blood drawn at a TrialNet site.
- We can send you a test kit. You take the test kit to your doctor or local lab to have your blood drawn, and then you send it to us.

We will have the results in 4 to 6 weeks.

What do my results mean?

Negative for Autoantibodies

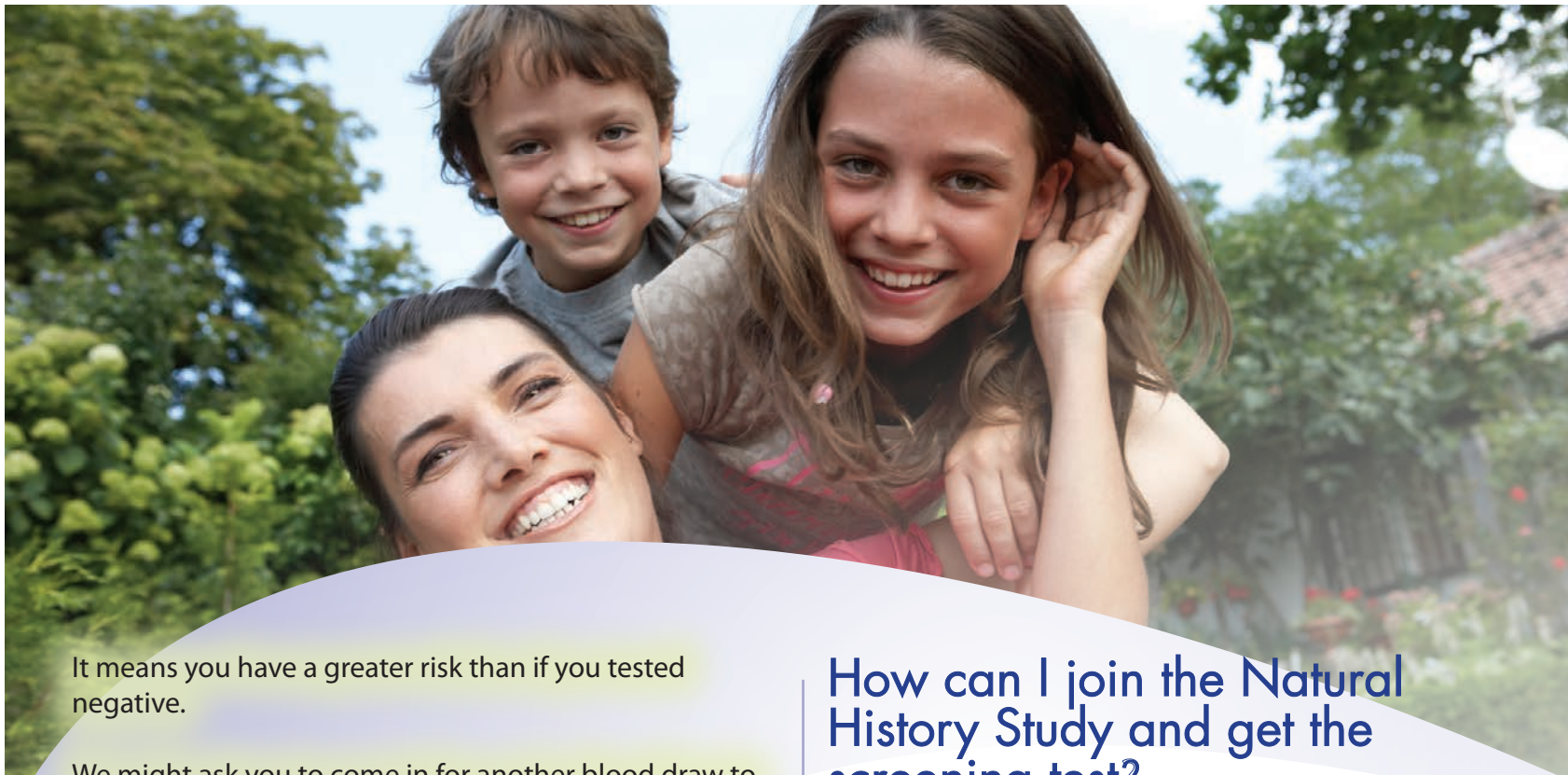
If your results are negative, we will send you a letter. Over 95% of the people we test are negative for signs of increased risk.

Testing negative does not mean you will never get diabetes. But your risk is much lower than if you had tested positive. That might change. So if you are under 18 years old, you can be screened every year.

We might contact you in the future to see if you want to take part in another diabetes study. We also want to know if you develop type 1 diabetes.

Positive for Autoantibodies

If you test positive, we will call you. Testing positive does not mean that you will get type 1 diabetes.



It means you have a greater risk than if you tested negative.

We might ask you to come in for another blood draw to confirm the results. This test should be done within 3 months.

If you are at increased risk, we will ask you to join the monitoring part of the Natural History Study. You will come in once or twice a year for blood tests.

If at any time you are eligible for another study, we will let you know. TrialNet offers studies testing ways to delay and prevent type 1 diabetes, as well as studies to delay progression once diabetes is diagnosed.

How can I join the Natural History Study and get the screening test?

Before you have the screening test, we will ask you to read the Informed Consent and sign it. This gives us your permission to do the test. Parents must give permission for children under 18 years old.

We will talk to you about the study, but it is important that you read the Informed Consent. If you have questions or concerns, please talk to us.

? What is TrialNet



TrialNet is a network of 18 clinical centers working with more than 200 screening sites throughout the United States, Canada, Finland, United Kingdom, Italy, Australia, and New Zealand. This network is dedicated to the study, prevention, and early treatment of type 1 diabetes. TrialNet is supported by the National Institutes of Health, which is part of the United States federal government. It is also supported by other major diabetes organizations.

www.DiabetesTrialNet.org

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