T1D RELAY

Type 1 Diabetes TrialNet

A study for those newly diagnosed with T1D

About the T1D RELAY Study

TrialNet is studying the use of rituximab-pvvr and abatacept, one after the other, to learn if using both treatments extends insulin production in people newly diagnosed with type 1 diabetes (T1D).

Previous studies with similar treatments showed people can make more insulin for a longer period of time while receiving either of the treatments. T1D RELAY will study if two treatments consecutively performs better than rituximab-pvvr alone. Researchers will test if those who are also treated with abatacept have better C-peptide levels over time.

Who Can Participate

This study is enrolling children and adults who are:

- Age 8-45
- Newly diagnosed with T1D (in past 3 months)

AND have:

- 1 or more diabetes-related autoantibodies
- C-peptide detectable during a mixed-meal tolerance test (MMTT)

To be in the study, you will need to be up to date on vaccinations including COVID-19 and flu.

TrialNet Locations

Study treatment will be available to residents in countries with participating TrialNet sites. For those willing to travel, assistance is available to help you get to the nearest location.

Quick Facts

Each treatment used in this study is FDA-approved to treat autoimmune conditions such as Rheumatoid Arthritis.

Rituximab-pvvr

Rituximab-pvvr is a monoclonal antibody. It reduces B cells.

Abatacept

Abatacept is a fusion protein treatment. It blocks a specific step in T-cell responses.

C-peptide

Measurements of C-peptide show how much insulin the body is making on its own, even if someone gets insulin from injections or a pump.

Sign up for the study here:

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Treatment

In the treatment phase, you or your child will receive four doses of rituximab-pvvr, given once per week by intravenous infusion in an arm vein.

Three months after your last rituximab-pvvr dose, you will be given a supply of syringes filled with abatacept or placebo (looks like the study treatment but is inactive) and taught how to inject it under the skin. You will need to give injections to yourself or your child once per week for 20 months.

Blood Sugar Monitoring

Participants in this study will wear a continuous glucose monitor (CGM) for 10 days after each study visit, including the initial screening visit. If you don't have a CGM, we will provide one.

Study Visits

You will have study visits during and between treatments where we will monitor your health. You will also continue to have study visits for 24 months after your last dose of the study treatment.

During some study visits, you will have a Mixed Meal Tolerance Test (MMTT) to measure how much insulin your body is making. The MMTT consists of drinking a liquid meal containing proteins, fats and carbohydrates, followed by a series of blood draws. An intravenous (IV) catheter is used for the blood draws, so there's only one poke while small samples are collected. There is a MMTT at the screening visit.

Ongoing Follow-Up

As part of the TrialNet family, we'll continue to follow you when this study is over. Your continued participation will be vital to helping us answer important questions about how T1Ddevelops and finding treatments to slow its progression.

Ask TrialNet

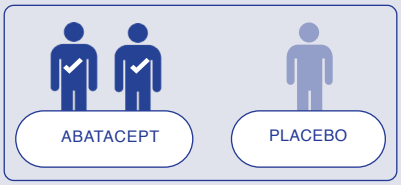
Have questions or need more information?

Contact: TrialNet ANZ
Phone: (03) 9342 7063
Email: Type1Screen@mh.org.au

Study Design

Everyone in the study receives rituximab-pvvr

2 out of 3 people will also receive abatacept



Placebo is an inactive version of the study treatment.

Randomized

A computer randomly selects who gets the study treatment (abatacept) and who gets the placebo. Neither you nor your doctor get to choose.

Before you join the study, the TrialNet research team will explain the study in detail, including study risks and benefits, and answer all your questions.

Sign up for the study here: