About the JAKPOT T1D Study

TrialNet is testing two different Janus kinase (JAK) inhibitors to see if either or both can preserve insulin production in people recently diagnosed with type 1 diabetes (T1D).

The two JAK inhibitors being tested in this study are abrocitinib and ritlecitinib. To understand which treatment works best, participants will be randomly assigned to one of three groups: one group will get abrocitinib, one will get ritlecitinib, and one will get a matching placebo (looks like the study treatment but has no active ingredients).

Who Can Participate

This study is enrolling people who are:

- Age 12-35
- Newly diagnosed with T1D (in past 3 months)

AND have:

- 1 or more diabetes-related autoantibodies
- Hemoglobin A1C below 10%
- 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

This study will be available at TrialNet sites in North America.

Quick Facts

JAK inhibitors

JAK inhibitors are a new type of treatment researchers are studying in people who have autoimmune conditions.

Researchers believe JAK inhibitors may be able to calm the immune system's attack on insulinproducing beta cells.

Beta cells

Located in the pancreas, beta cells are the only cells in the human body that can make insulin.

C-peptide

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

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JAKPO'



Treatment

You will take an oral tablet daily for 1 year.

(a) Monitoring

Participants in this study will wear a continuous glucose monitor (CGM) for 2 weeks after each visit, including the initial screening visit. If you don't have a CGM, we will provide you one.

Study Visits

For the first year of the study, you will visit a study site every 3 months for tests and monitoring. In the second year, you will visit the study site every 6 months.

During most 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 blood draw. An intravenous (IV) catheter is used for the blood draw, so there's only one poke while small samples are collected over 2 hours.

Ongoing Follow-Up

When this study is over, we will invite you to participate in longterm monitoring. Your continued participation is vital to helping us answer important questions about how T1D progresses and learn more about any long-term effects of your participation in this study.

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.

Ask TrialNet

Have questions or need more

information?

Children's Mercy site contact:

Krystin Quilty Sanford trialnet@cmh.edu

Study Design

Placebo-controlled

2 out of 3 people will receive a type of study treatment



Placebo is an inactive version of the study treatment.

2 Types of Study Treatment

Abrocitinib or Ritlecitinib

Randomized

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

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