

JAK Inhibitors to Preserve C-Peptide Production in New Onset T1D: A Phase 2 Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Subtype-Selective JAK Inhibitors for Preservation of Pancreatic Cell Function in Newly Diagnosed Type 1 Diabetes Mellitus

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: Not specified

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- age 12-35 years (inclusive) - diagnosis of T1D within 100 days of first study visit - positive for at least one islet cell autoantibody - HbA1c no more than 10 % - body weight at least 35kg (77 pounds) - willing to comply with intensive diabetes management and wear a Continuous Glucose Monitoring Device (CGM) - up to date on recommended immunizations (including flu and COVID-19) - willing to use highly effective contraception for 3 months after the last dose of study medication

Exclusion Criteria:

- current use of a medication that affects glucose control - treatment with other immunosuppressive agents (including biologics or steroids), other than inhaled or topical glucocorticoids - current history of infection (HIV, Hepatitis B, TB, herpes etc.) - current or past use of tobacco or nicotine containing products more than the equivalent of 5 cigarettes per day - current or past medical or mental health conditions (study staff will review) - women who are pregnant, breast feeding, or planning to become pregnant

Conditions & Interventions

Interventions:

Drug: Abrocitinib 200 MG Oral Tablet, Drug: Placebo, Drug: Ritlecitinib

Conditions:

Children's Health, Diabetes & Endocrine

Keywords:

T1D, new onset, type 1 diabetes,

More Information

Description: This is a new type 1 diabetes onset study for ages 12-35 years old. We are looking at JAK inhibitor drugs to see if they can preserve beta cell function.

Study Contact: Kali Johnson - joh13933@umn.edu

Principal Investigator: Antoinette Moran

IRB

Number: SITE00001949

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