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Patient Care + Research + Clinical Trials

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Baricade-Preserve T1D newly-diagnosed study

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Study location: BCDiabetes: 400 - 210 West Broadway, Vancouver V5Y 3W2

Summary: Baricade-Preserve is a Phase 3, Double-Blind, Randomized,Placebo-Controlled study of Baricitinib–a JAK inhibitor, to preserve Beta cell function in newly-diagnosed Type 1 Diabetes aged ≥1 to <36 years. The trial will run for approximately 60 weeks, comprising 13 on-site visits from screening to safety follow-up. Participants will receive either 4mg or 2mg baricitinib or matching placebo, to be taken orally (tablet/oral suspension) daily for 52 weeks.

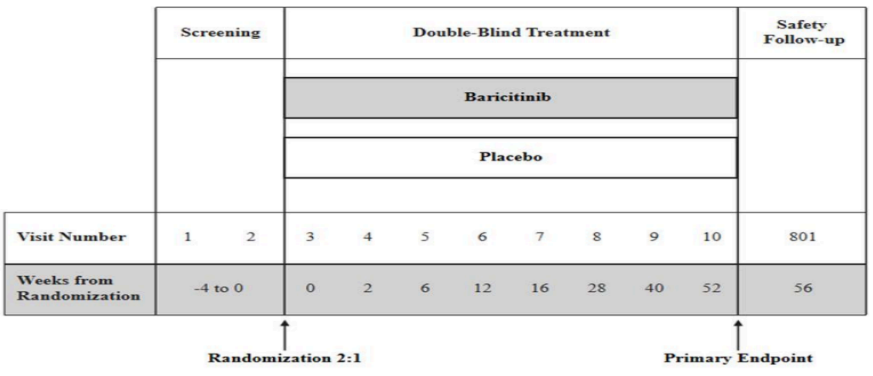
Hypothesis: Type 1 diabetes (T1D) is characterized by autoimmune destruction of the insulin producing pancreatic β cells. To optimize preservation of β cell mass and function, it is essential to intervene early in the course of the disease by targeting the autoimmune mechanism and thus preventing further destruction of the remaining β cells. **Baricitinib** is a JAK inhibitor that has immunomodulatory and anti-inflammatory effects. Direct and indirect evidence showed that baricitinib can preserve β cell function by blocking the JAK pathway which is involved in T1D pathogenesis.

Eligible Participants include:

- **Individuals aged ≥1 to <36 years of age**
- **Newly-diagnosed T1D (within 100 days prior to starting study intervention)**
- **Have at least one diabetes-related autoantibody (GADA, IAA, IA2A, ZnT8A)**
- **Stimulated C-peptide ≥0.2nmol/L or Random C-peptide >0.3nmol/L**
- **Body weight ≥8 kg; BMI < 35; Bone age X rays for < 18 yrs of age**

Treatment course and duration: The study consists of 3 periods: 4-week screening period (V1-V2), 52-week treatment period (V3-V10) and a 4-week safety follow-up period (V801). Randomized participants will take either 4mg or 2mg baricitinib or matching placebo orally daily during the treatment period. V2 (stimulated C-peptide), V3, V6 and V8-V10 are fasting visits with 2-hr MMTT.

Odds of receiving placebo: 33% (one third)



Study documents:
Informed Consent
Conflict of Interest statement
Short URL = https://bit.ly/baricadeT1_2