bcdiabetes.ca
Patient Care + Research + Clinical Trials

Dr. Tom Elliott MBBS, FRCPC
Medical Director

400 - 210 W Broadway
Vancouver, BC
V5Y 3W2 Canada

phone: 604.683.3734
fax: 604.628.3821
email: moa@bcdiabetes.ca

Baricade-Delay T1D at-risk study

Principal Investigator: Dr. Tom Elliott **SubInvestigator**: Dr. Dale Clayton
Study coordinator & primary contact Marla Inducil MD, Hector Com MD, Glaiza Erfe MD
P: 604-628-7253 x 7011, minducil@bcdiabetes.ca ; gerfe@bcdiabetes.ca

Summary: Baricade-Delay is a Phase 3, Double-Blind, Randomized, Placebo-Controlled study of baricitinib to delay onset and diagnosis of Stage 3 Type 1 Diabetes in at-risk participants (Stage 1b or Stage 2) aged ≥1 to <36 years

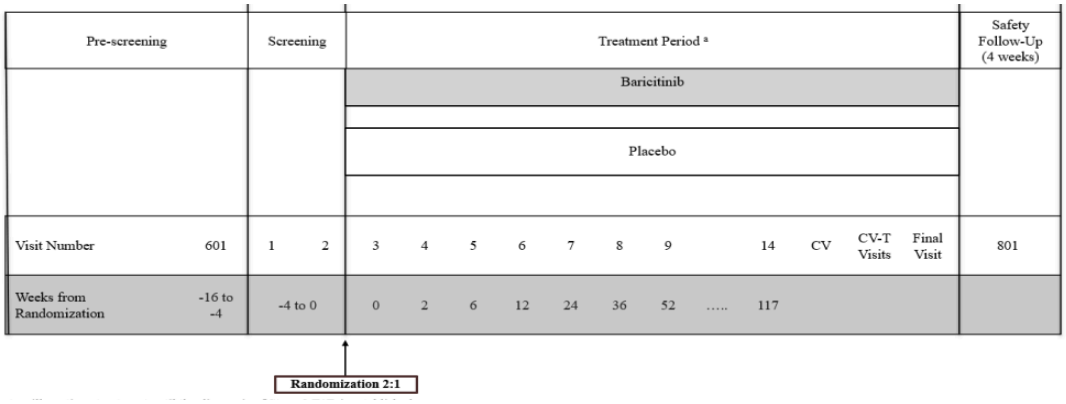
Study location: BCDiabetes: 400 - 210 West Broadway, Vancouver V5Y 3W2

Hypothesis: Type 1 diabetes (T1D) is characterized by autoimmune destruction of the insulin producing pancreatic β cells. Screening and identification of islet autoantibody positive individuals has resulted in the recognition that T1D is a continuum of stages with genetic risk and autoimmunity (Stages 1 and 2) preceding the development of Stage 3 T1D (fully-blown T1D). The goal of an effective therapeutic for the delay of Stage 3 T1D is intervention to preserve β cell function. **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**
- **at least one documented occasion of at least 2 diabetes-related autoantibodies**
- **Meet definition for Stage 2 T1D dysglycemia or Stage 1b T1D**
- **any one of: A1C 5.7-6.4%; Fasting BG 6.1 - 6.9; 2 hr BG 7.8 - 11.1 or 10% rise in A1c**
- **body weight ≥8 kg; BMI < 35**

Treatment course and duration: This study consists of an optional prescreening period (at least 12 weeks before screening), 4-week screening period (V1-V2), a 117-week treatment period (V3-V14) where participants will take 4mg or 2mg of baricitinib or placebo orally daily, and a 4-week safety follow-up period. Participants will continue with the treatment until the diagnosis of Stage 3 T1D is established. Those who do not develop Stage 3 T1D after week 117 will have continuation visits (CV) every 26 weeks and continuation visit-telehealth (CV-T) every 13 weeks after CV, until the last visit criteria is met.



Odds of receiving placebo: 2:1 (4mg or 2mg baricitinib : 4mg or 2mg placebo)

Study documents:

Informed Consent

Conflict of Interest statement

Short URL = https://bit.ly/baricadeT1