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

Ustekinumab RCT- UST1D2 A Clinical phase II/III trial in newly diagnosed Type 1 diabetes aged 18-35

Study location BCDiabetes: 400 - 210 West Broadway, Vancouver V5Y 3W2
Principal Investigators Drs. Tom Elliott (Vancouver) and Bruce Perkins (Toronto)
Study coordinator & primary contact Dr. Marla Inducil P: 604-628-7253 x 7011 : minducil@bcdiabetes.ca

Summary:

UST1D2 is a phase II/III randomized controlled trial of the effectiveness of ustekinumab (drug:placebo ratio of 2:1) in newly diagnosed Type 1 diabetes aged 18-35 years.

Hypothesis:

Ustekinumab delays the loss of β-cells and maintains a clinically relevant level of β-cell function in young adults with newly diagnosed with T1D.

Eligible Participants include:

- Male or female aged 18-35 years at randomization diagnosed with T1D by ADA criteria.
- Ability to receive the first dose of study drug within 100 days of diagnosis of T1D.
- Positive for ⩾1 T1D autoantibody (GAD65, IA-2A, miAA or ZnT8A) & peak stimulated C-peptide ⩾0.2 pmol/ml

Treatment course and duration:

Ustekinumab or matching placebo will be administered via IV infusion at a loading dose of 6 mg/kg given at week 0. Thereafter 90 mg Ustekinumab/PBO will be given SC at weeks 8, 16, 24, 32, 40 and 48 (7 doses total). Total duration of study is 78 weeks, In order to quantitate endogenous B cell function, a 2hr MMTT will be conducted at screening , week 28, 52 and 78 for key endpoint assessment.

Odds of receiving placebo ⅓ (33%)

Other notes

All subjects will be provided CGM (Dexcom G6) at no charge for the full 18 months of the study. Grants to help cover the costs of accommodation & travel to Vancouver or Toronto from anywhere in Canada are available.

Study documents:

Protocol
Consent form
Ethics Approval Ethics renewal
Short URL to this document: https://bit.ly/T1DRCT