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Patient Care + Research + Clinical Trials

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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)
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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, necessitating 10 trips to the site, 4 trips requiring an overnight stay. 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%)

Freebies, travel and accommodation subsidies
All subjects will be provided a CGM (Dexcom G6 or G7) at no charge for the first 12 months of the study. For Canadian residents full reimbursement for travel & accommodation expenses to Vancouver or Toronto from anywhere in Canada is available upon request.
For US or international potential participants a total subsidy for travel and accommodation of US$4000 for the 10 trips to Vancouver (equivalent to US$400 per trip) may be available.

Study documents:
Protocol Consent form Ethics Approval Ethics renewal
Conflict of Interest statement
Short URL to this document: https://bit.ly/T1DRCT