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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, Canada
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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 (⩾0.2 nmol/L, ⩾60 ng/100ml)

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, To quantitate endogenous B cell function, a 2hr MMTT will be conducted at screening, and weeks 28, 52 and 78.

Odds of receiving active drug ⅔ (66%) Odds of receiving placebo ⅓ (33%)

Duration of study - 18 months
Number of visits: 10 - the longest visit is 4 hours. Four of the visits require fasting for 8+ hours.

Other notes
All subjects will be provided CGM (Dexcom G6/G7) at no charge for the full 18 months of the study. Grants to help cover the costs of accommodation & travel to Vancouver from the continental United States are available.

Study documents:
Protocol
Consent form
Ethics Approval Ethics renewal
Short URL to this document: https://bit.ly/VancouverT1D