bcdiabetes.ca
Patient Care + Research + Clinical Trials

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COVALENT-112 Menin inhibition in T1D

The study described below is no longer recruiting. As of 2025-Mar-31, a follow-on study with icovamenib in individuals with Type 1 diabetes of duration < 12 months is being considered by the sponsor. For updates on this potential study email questions@bcdiabetes.ca or become a client of BCDiabetes in which case you will be automatically notified.

Study location BCDiabetes: 400 - 210 West Broadway, Vancouver V5Y 3W2
Principal Investigator Dr. Tom Elliott
Study coordinator & primary contact Alireza Moshiri MD P: 604-628-7253 x 7011

Investigational new drug:
Icovamenib, a covalently bound reversible inhibitor of menin, the protein product of the MEN gene
Hypothesis: icovamenib is safe, increases C-peptide and lowers A1c by improving insulin secretion

Inclusion criteria
male & female age 18-60 duration 0.1-15 years on insulin (no other diabetic drugs)
BMI < 40, A1c 6.5-10.0, 1+ diabetes autoAb (GAD65, iAAb, insulin autoAb, ZnT8Ab)
If duration <3 years, fasting or MMTT-stimulated C-peptide ≥0.2nM/L (0.60 µg/L)
If duration 3-15 years, fasting or MMTT-stimulated C-peptide ≥0.08nM/L (0.24 µg/L)

Exclusion criteria
Advanced diabetic neuropathy, history of gastroparesis, 2+ episodes severe hypoglycemia last 6 months
Cigarette smoking > 5 cigs per day, Vascular event within 6 months
+v drug screen including MJ or poppy seed-containing products *poppy seed cake,bagels etc allowed)
Actively dieting or use of GLP-1 or diet drug within 2 month prior to screening
Use of corticosteroids, PPIs, other diabetes Rx within 5 half-lives prior to screening
Use of CYP3A4 inhibitors
eGFR < 60, lipase or amylase >1.5*ULN
HBV, HCV, cirrhosis of any cause, HIV, untreated Celiac disease

Study design:
The study lasts 52 weeks. A daily oral version of icovamenib is taken for the first 12 weeks; the last 40 weeks no medication is taken. Monthly in-person visits will be required, each visit lasting 4-6 hours during which time an IV will be inserted and blood samples drawn hourly.
(note - open-label studies with 40 participants completed enrollment 2024-05-09)
150 subjects with T1 duration 0.1 -15 years, will be randomized 1:1:1 between Arms A, B & C beginning ?Fall 2024 and receive study drug once daily for 12 weeks
Arm A will receive icovamenib 100 mg daily, Arm B will receive 200 mg daily and Arm C will received matching placebo

Study documents:
Protocol Ethics Approval Informed Consent Form (ICF)

Other documents:
Dr. Elliott's conflict of Interest statement
Dr. Elliott's 5 minute YouTube on the science behind menin-inhibition and beta cell regeneration
BCDiabetes' Dr. Kate Hawke's 3 minute YouTube on why menin inhibition by icovamenib is unlike the zero menin state of MEN1 syndrome

Short URL to this document: https://bit.ly/BiomeaT1