bcdiabetes.ca
Patient Care + Research + Clinical Trials

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FINE-ONE Finerenone on T1DM with CKD A

parallel-group, randomized, prospective, interventional, double-blind, Phase 3 study to investigate the efficacy and safety of finerenone versus placebo, in addition to standard of care, in participants with chronic kidney disease and type 1 diabetes

Study location BCDiabetes: 400 - 210 West Broadway, Vancouver V5Y 3W2
Principal Investigators Drs. Tom Elliott and David Lee
Study coordinator & primary contact Dr. Marla Inducil P: 604-628-7253 x 7011 : minducil@bcdiabetes.ca
Summary: FINE-ONE is a Phase 3, 36 week, double-blind trial of finerenone compared to placebo, in addition to SoC, in delaying the progression of CKD in participants with CKD and T1D. Change in UACR from baseline (ratio to baseline) over 6 months is its primary endpoint. (drug:placebo ratio of 1:1)
Hypothesis: To demonstrate the efficacy of Finerenone (10 or 20 mg based on eGFR) compared to placebo in reducing UACR used as a bridging biomarker to demonstrate slowing of kidney disease progression without hyperkalemia.
Eligible Participants include:

- Male or female >18 yrs of age
- T1DM > 1 year
- A1c< 10%
- K+ ≤4.8
- UACR ≥22.6 to 565 mg/mmol
- eGFR ≥25 and <90 mL/min/1.73 m2
- No dual therapy ACEi/ARB; No SGLT2 inh; GLP1; K sparing diuretic

Treatment course and duration: 7 monthly visits over 36 weeks
Odds of receiving placebo:(50%)
Study documents:
Protocol
Consent form
Ethics Approval
Short URL to this document: https://bit.ly/FINE-ONE_T1