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

Principal Investigator: Dr. Tom Elliott **SubInvestigator**: Dr. Dale Clayton
Study coordinator & primary contact Glaiza Erfe MD P: 604-628-7253 x 2014
gerfe@bcdiabetes.ca

Summary:
AZ NCT06268873 is a Phase III, randomised, double-blind, active-controlled study to assess the efficacy, safety and tolerability of baxdrostat in combination with dapagliflozin compared with dapagliflozin alone (drug:placebo = 1:1) on the progression of chronic kidney disease (CKD) in subjects with CKD and high blood pressure.

Study location BCDiabetes: 400 - 210 West Broadway, Vancouver V5Y 3W2

Hypothesis: Baxdrostat is a highly selective aldosterone synthase inhibitor that can significantly reduce aldosterone levels, offering the potential to not only improve BP in patients with CKD, but also ameliorate the negative impacts of elevated aldosterone on kidney function. On the other hand, sodium-glucose cotransporter-2 inhibitors have been demonstrated to reduce the risk of sustained kidney function decline, kidney failure, and CV death in patients with CKD and diabetes. As baxdrostat and dapagliflozin have different and complementary mechanisms of actions, their combination is anticipated to provide additive benefits in slowing the progression of CKD. Combination therapy is expected to improve CKD outcomes via BP-dependent and BP-independent pathways and also expected to provide additional benefit by reducing the risk of hyperkalaemia.

Eligible Participants include:

- Male or female aged ≥ 18 years
- eGFR ≥ 30 and < 90 mL/min/1.73 m2 and UACR > 56.5mg/mmol and <565mg/mmol
- Systolic BP ≥ 130 mmHg
- Serum Potassium ≥3.5 and ≤ 4.8 mmol/L

Treatment course and duration: This study consists of a screening visit, a 4-week dapagliflozin run-in period for participants naïve to SGLT2i at baseline, a 24-month double-blind treatment period in which participants will receive either baxdrostat/dapagliflozin or dapagliflozin and a 6-week open-label period in which all participants will discontinue baxdrostat/placebo and receive dapagliflozin alone.

Odds of receiving placebo : 1:1 (10mg dapagliflozin + 1mg baxdrostat (can be titrated to 2mg) : 10mg dapagliflozin + placebo)

Study documents:

Informed Consent
Protocol
Conflict of Interest statement

Short URL = https://bit.ly/BCDbaxduo