

Oral GLP1 in Participants Type 2 Diabetes (Eluminate 3)

Study location: [BCDiabetes: 400 - 210 West Broadway, Vancouver V5Y 3W2](#)

Principal Investigators: Dr. Tom Elliott **SubInvestigators:** Drs. Dale Clayton & Dae Won (David) Lee

SC & Primary Contact: Marla Inducil MD P: 604-628-7253 x 7011 : minducil@bcdiabetes.ca

Back up SC: Hector Com MD ; Glaiza Erfe MD; Alireza Moshiri MD

Summary: The purpose of this 58 week trial is to evaluate the efficacy, safety, and tolerability of once-daily oral administration of elecoglipron, a small molecule, compared with oral semaglutide, a peptide molecule, in adults with type 2 diabetes mellitus (T2DM) Mellitus with a stable dose of Background Insulin (Eluminate-3) and up to 2 oral glucose-lowering medications (metformin, SGLT2i, nateglinide, SU, and/or AGI).

Hypothesis: Elecoglipron, a novel small-molecule oral GLP-1 RA, is anticipated to provide efficacy and safety comparable to other GLP-1 RAs but with the added convenience of oral administration and no fasting requirements, thus potentially improving access and adherence to therapy. The established pharmacology of GLP-1 RAs, including semaglutide, along with data from elecoglipron early clinical studies, supports the expectation that elecoglipron will provide benefits in both glycemic control and weight loss. Participants may also experience improved metabolic control such as reductions in lipids and BP.

Eligible Participants: include

- ≥ 18 yrs of age
- T2DM (on stable insulin + up to 2 oral Hypoglycemic agents
- A1c 7% to ≤ 10.5%
- default atorvastatin 20 mg OD
- BMI ≥ 23 kg/m2

Odds of receiving active drug: 1:1:1 - 45 mg: 65 mg elecoglipron: PBO x 52 weeks

	Pre-screening (optional) ^a	Screening Visit	Randomization and titration period, restricted insulin escalation ^b							Treatment period, restricted insulin escalation ^b				12 week extension period, adjustable insulin period ^b		EoT	FU ^c	WOCBP phone visits ^d	EDV ^e	Details in CSP section or appendix
Visit number		1	2 ^f	3	4	5	6	7	8	9	10	11	12	13	14					
Study week		-4	0	4	8	12	16	20	24	32	40	44	48	52	54					
Study day and visit window (days)		-28 to -1	1	29	57	85	113	141	169	225	281	309	337	365	379			± 3 ^d	+ 14	
Phone Visit (all participants)					± 3	± 3	± 3	± 3	± 3	± 3	± 7	± 7	± 7	± 7	± 3 ^e					
Fasting visit ^e			X			X			X		X			X					X	

Informed Consent:

Short URL: <https://bit.ly/4uNgMV3>