bcdiabetes.ca
Patient Care + Research + Clinical Trials

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SELENE 3

Lenbelintide added to incretin-based therapy in obese or overweight individuals with or without Type 2 Diabetes Mellitus

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

Summary: This is a Phase III randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of the amylin analogue lenbelintide administered SC once weekly as an add-on intervention to existing GLP-1 treatment, with the potential for additional weight loss benefit. Odds of receiving lenbelintide are 66% (⅔). Odds of receiving placebo (a nothing drug) are 33% (⅓).

Background & hypothesis: Endogenous amylin is a hormone co-secreted with insulin into the bloodstream by pancreatic β-cells. Lenbelintide is a potent selective agonist of amylin receptors with a longer half-life and flatter PK profile. In this study lenbelintide will be added to subjects already taking incretin-based therapies and is expected to provide a boost helping to achieve greater long-term, high quality weight loss benefits, which could potentially be achieved via selective fat mass reduction and preservation of lean muscle mass

Eligible Participants:
● ≥ 18 yrs of age on any weekly GLP1a at the following stable doses:
SC semaglutide (≥ 1.7 mg);oral semaglutide (25 mg); tirzepatide (≥ 5 mg)
● BMI ≥ 30 kg/m2 OR BMI ≥ 27 kg/m2 with at least one weight-related comorbidity (i.e. hypertension, dyslipidemia, OSA, cardiovascular disease, heart failure, chronic kidney disease, metabolic dysfunction-associated steatotic liver disease, osteoarthritis of the knee, or stress urinary incontinence.)
● For T2DM A1c of ≥ 6% - ≤ 9% on diet and exercise or on oral hypoglycemic agents; no insulin

The study consists of a 13Wks of titration period and 56Wks of full treatment, for a total of 69 weeks of intervention and 1 follow up visit 4 weeks after the last injection. See visit distribution below

Screening		Day 1	Titration period						Treatment period							F/U
Visit	V1 *	V2 *	V3	V4	V5	V6 *	V7 *	V8 *	V9 *	V10	V11	V12 *	V13 *	V14 *	V15 *	V16 *
WK	Scr	Day 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 9	Wk 13	Wk 17	Wk 21	Wk 25	Wk 29	Wk 41	Wk 53	Wk 69	Wk 73
Visits with (*) requires blood draw																

Study documents:

Short URL https://bit.ly/43qIfjz