bcdiabetes.ca
Patient Care + Research + Clinical Trials

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The EMBOLD Trial: oral GLP-1 elecoglipron in obesity +/- Type 2 diabetes

Study location BCDiabetes: 400 - 210 West Broadway, Vancouver V5Y 3W2
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Summary:.This trial covers 2 independent Phase III pivotal studies, D7260C00015-Study 1 (hereafter referred to as “Study 1”) and D7260C00015-Study 2 (hereafter referred to as “Study 2”), to evaluate the efficacy and safety of elecoglipron compared with placebo in:
• Study 1: Participants living with obesity or overweight with at least one weight-related comorbidity (hypertension, prediabetes, dyslipidemia, cardiovascular disease, obstructive sleep apnea) and without type 2 diabetes mellitus (T2DM)
• Study 2: Participants living with obesity or overweight with T2DM

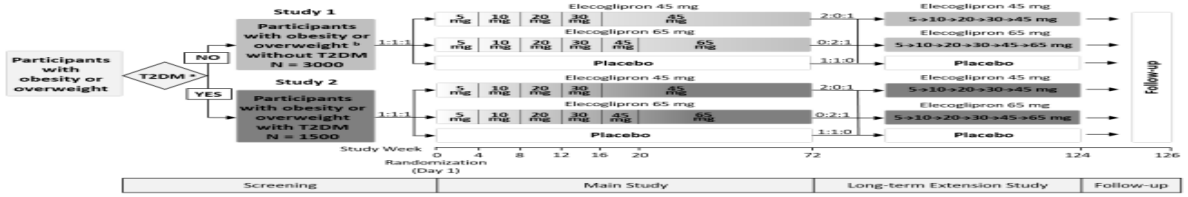
Hypothesis:

Eligible Participants include:

- Male or female ≥18 yrs of age
- Study 1 - Overweight (BMI≥ 30) or BMI 25 kg/m2 ≤ BMI < 30 kg/m2 + 1 comorbidity
  Study 2 - Overweight (BMI ≥ 25) with T2DM treated with diet and exercise or OHA OR without T2 DM and A1c ≥6.5 %; Participants with HbA1c < 8.5% may proceed with randomization provided all other criteria met; Participants with A1c > 8.5% and overt signs/symptoms of hyperglycemia must be rescreened after a 90-day period, during which they should receive standard of care glucose management except GLP-1 RA containing medications.

Treatment course and duration: The estimated maximum study follow-up for participants is approximately 2.5 yrs.

Odds of receiving active drug are: 1:1:1 (45mg:65 mg:pbo)



Study documents:
Short URL = https://bit.ly/4vYChDo