

ZUCARA A Phase 2a, Randomized, Double-blind, Placebo-controlled, Multiple-dose, Crossover Study of the Effect of ZT-01 on Frequency of Nocturnal Hypoglycemia in Type 1 Diabetes Mellitus

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

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Summary: ZONE ZT01-CL-2001 A Phase 2a study of effect of 3 dose levels 7, 15, 22 mg of ZT-01 and placebo administered subcutaneously (SC) daily at bedtime for 28 days on incidence of nocturnal hypoglycemia in subjects using CGM with T1DM.

Hypothesis: ZT-01 will reduce hypoglycemic events. ZT-01 is a cyclic octapeptide analog of somatostatin with highly selective antagonist activity at the somatostatin receptor subtype 2 (SSTR2). In animal models, SSTR2 antagonists enhance the impaired glucagon counterregulatory response to hypoglycemia and reduce the incidence of hypoglycemia in response to repeated insulin challenge.

Eligible Participants include:

- Male or female 18- 75 yrs of age
- T1DM at least 5 yrs using MDI or non-automated insulin pump
- Recent history of hypoglycemia 00:00-06:00 hrs (≥ 4 events over 4 weeks) captured on CGM
- A1c $\leq 10\%$
- BMI 18.5-33 Kg/m²
- GFR >60
- BP $< 140/90$
- No DKA hospitalisation in the past 6 months

Treatment course and duration: if with CGM data 3 months prior to screen = 4 months; if no CGM = 6 months

Odds of receiving active drug are 100%: every participant will receive active drug for 1 month & placebo for 1 month though they won't know when they are receiving active vs placebo.

Study documents:

[Protocol](#) [Consent form](#) [Ethics Approval](#) [Ethics renewal](#)

[Conflict of Interest statement](#)

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