A Phase 2 Multi-Ascending Dose Trial to Assess the Efficacy, Tolerability and Pharmacokinetic Profile of Exendin (9-39) in Patients With Post-bariatric Hyperinsulinemic Hypoglycemia

Statistical Analysis Plan

NCT02771574

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Data are presented as mean ± SD. Insulin sensitivity was estimated by homeostatic model assessment of insulin resistance (HOMA-IR). Area under the curve (AUC) calculations were performed using the trapezoidal rule. Because of the potential cancelling effect of the early rise and late fall in plasma glucose and insulin when considered as AUC over 180 minutes, AUC values were partitioned into 0 to 90 (pre-glycaemic-peak) and 90 to 180 (post-glycaemic peak) minutes. Rate of glucose decline was calculated as (glucosepeak − glucosepeak + 30 min)/30 min. When the OGTT was stopped early because of hypoglycaemia requiring glycaemic rescue, the last glucose value recorded prior to rescue was carried forward. Plasma avexitide concentrations were collected twice daily for 3 days immediately prior to dosing, and over a 12-hour period on days 1 and 3 of dosing. Pharmacokinetic variables assessed include C0 (pre-dose concentration), Cmax (peak post-dose concentration), Tmax (time of Cmax), and AUC over a 12-hour period.