

The ASPIRE Study: Design and Methods of an In-Clinic Crossover Trial on the Efficacy of Automatic Insulin Pump Suspension in Exercise-Induced Hypoglycemia

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Abstract

Background:

The Paradigm[®] Veo[™] System includes a low glucose suspend (LGS) feature which suspends insulin delivery when a prespecified glucose threshold setting is reached by the associated continuous glucose monitoring (CGM) sensor. The ASPIRE (Automation to Simulate Pancreatic Insulin REsponse) study is a multicenter, in-clinic, randomized, crossover study to examine the efficacy of LGS in exercise-induced hypoglycemia.

Methods:

Insulin-pump users underwent two separate exercise sessions, one with the LGS feature set to suspend insulin (LGS-on) when the CGM-detected glucose concentration was ≤ 70 mg/dl and one with the LGS feature off. Exercise sessions were conducted after an overnight fast and with initial plasma glucose level as measured by the YSI 2300 STAT Plus glucose analyzer (YSI) of 100–140 mg/dl. Subjects exercised until their YSI value fell to ≤ 85 mg/dl; subsequent YSI values < 70 mg/dl were recorded for up to 4 h to measure the duration and nadir of hypoglycemia. The protocol required that subjects with YSI values < 50 or > 300 mg/dl were rescued with carbohydrates or insulin, respectively, based on the provider's recommendation. The primary end point was comparison of duration and severity of hypoglycemia between LGS-on and LGS-off sessions. Secondary end points included areas under the glucose concentration curve, CGM sensor accuracy, and last YSI glucose. Device- and procedure-related adverse events and serious adverse events were recorded.

Results:

Fifty adults and teenagers (17–58 years) with type 1 diabetes were randomized. Study completion is expected in November 2011.

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Abbreviations: (ASPIRE) Automation to Simulate Pancreatic Insulin Response, (BG) blood glucose, (CEC) Clinical Events Committee, (CGM) continuous glucose Monitoring, (IRB) Institutional Review Board, (LGS) low glucose suspend, (SD) standard deviation, (YSI) plasma glucose concentration as measured by the YSI glucose analyzer

Keywords: exercise-induced hypoglycemia, low glucose suspend, semi-closed loop, sensor-augmented insulin pump, Veo insulin pump

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Abstract cont.

Conclusions:

Results may establish the efficacy of the LGS feature of the Veo sensor-augmented pump system in reducing the duration and severity of exercise-induced hypoglycemia.

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