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ORIGINAL ARTICLE

ASPIRE In-Home: Rationale, Design, and Methods of a Study to Evaluate the Safety and Efficacy of Automatic Insulin Suspension for Nocturnal Hypoglycemia

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Abstract

Nocturnal hypoglycemia is a barrier to therapy intensification efforts in diabetes. The Paradigm® Veo™ system may mitigate nocturnal hypoglycemia by automatically suspending insulin when a prespecified sensor glucose threshold is reached. ASPIRE (Automation to Simulate Pancreatic Insulin REsponse) In-Home (NCT01497938) was a multicenter, randomized, parallel, adaptive study of subjects with type 1 diabetes. The control arm used sensor-augmented pump therapy. The treatment arm used sensor-augmented pump therapy with threshold suspend, which automatically suspends the insulin pump in response to a sensor glucose value at or below a prespecified threshold. To be randomized, subjects had to have demonstrated ≥2 episodes of nocturnal hypoglycemia, defined as >20 consecutive minutes of sensor glucose values ≤65 mg/dl starting between 10:00 PM and 8:00 AM in the 2-week run-in phase. The 3-month study phase evaluated safety by comparing changes in glycated hemoglobin (A1C) values and evaluated efficacy by comparing the mean area under the glucose concentration time curves for nocturnal hypoglycemia events in the two groups. Other outcomes included the rate of nocturnal hypoglycemia events and the distribution of sensor glucose values. Data from the ASPIRE In-Home study should provide evidence on the safety of the threshold suspend feature with respect to A1C and its efficacy with respect to severity and duration of nocturnal hypoglycemia when used at home over a 3-month period.

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Abbreviations: (A1C) glycated hemoglobin, (AUC) area under the curve, (CGM) continuous glucose monitoring, (FDA) Food and Drug Administration, (HFS) hypoglycemia fear survey, (LGS) low glucose suspend

Keywords: ASPIRE, insulin pump suspension, low glucose suspend, nocturnal hypoglycemia, randomized controlled trial, threshold suspend

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