New Hybrid Closed Loop (HCL) Fuzzy Logic Investigational Device

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Abstract

To assess the safety and effectiveness of a revised (v2.3) Dose Safety fuzzy logic controller (FLC) when used in HCL mode on a new iPhone ambulatory investigational device.

Protocol

The CRC study ran from 0830-1530; a 75g CHO meal was given at 1100. Study included testing the robustness of the device by creating CGM and pump wireless communication failures. The new investigational device uses an iPhone, Dexcom G4 CGM and an Insulet OmniPod pump. Seven studies were completed.
The FLC dosing algorithm is designed to run 24-hours per day as a fully automated closed loop (FACL) dosing algorithm. It doesn't have a meal CHO input or meal notification. To prevent over-insulinization after the manual bolus the device suspends FLC dosing when a manual insulin bolus is detected, then resumes FACL dosing after 105 minutes.

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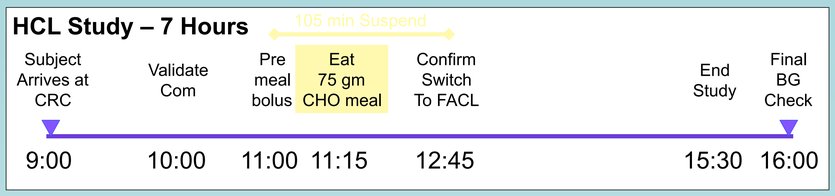
Time Line



Demographics

N=7, 4 female, 3 male
Age (yrs) 32.3 (SD 9.5)
HbA1c 7.1% (SD 0.92%)
T1D duration (yrs) 9.0 (SD 4.2)

Results

% time < 70mg/dL 0.5%
% time 70-180 mg/dL 68.2%
% time > 180 mg/dL 31.2%
% time > 250 mg/dL 14.2%
% time > mg/dL 8.5%
Mean glucose was 161.9 (SD 68.5).
The system uptime was 100%.

Results

Patient number	Start	Premeal	Premeal -Start	Peak	Resume FACL	Resume -Premeal	End	End -Resume
401	98	99	1	178	173	74	68	-105
403	123	89	-34	122	119	30	81	-38
404	179	121	-58	177	145	24	116	-29
405	131	136	5	191	170	34	122	-48
406	192	305	113	333	327	22	170	-157
407	195	156	-39	200	121	-35	149	28
408	199	194	-5	332	332	138	163	-169

Conclusion

Initial HCL performance, although from a very small number of subjects, is excellent. The new Dose Safety investigational device shows promise for use in upcoming hotel studies.