Medical University of Graz

Premature termination of a Clinical Trial

Full title of the clinical Trial: A Prospective, Single Center Post-Market Observational Study to Assess the Efficacy, Safety, and Patient Reported Outcomes of Insulin Delivery with PaQ® in Patients with Type 2 Diabetes Mellitus

EudraCT Number: 2013-004288-30

Sponsor: CeQur Corporation

Represented by (name): Leslie Lilly, BSN, RN

Reason for premature termination of the clinical trial:

This study was the first to use a fully functional Messenger with the capability to track length of time worn, sense occlusions, or to notify the wearer that the device was running out of insulin. There are four different Messages that are emitted when the Status Button is pushed (1, 2, 3 and 4 vibrations/buzz). The 4 buzz message communicates to the user that it is time to change the insulin reservoir because either 72 hours or three days have passed, the PaQ is out of insulin or the fluid path is clogged. In this study, there was a high frequency of 4 buzzes being emitted earlier than 72 hours. As instructed, users followed the instruction to replace the device. However, to investigate the performance of the PaQ system, the study was stopped after the enrollment and completion of 8 participants.

Study results (if available):

Primary Study Endpoint - HbA1c Change from Baseline Values:

The primary efficacy endpoint for this study was the change in HbA1c (obtained from venous blood) from Baseline at Week 12. A secondary endpoint was this same assessment, but at Week 8. A total of 8 patients were analyzed at Baseline and 7 patients were analyzed at Week 12, patient 01-005 had terminated early. At Week 12, a mean (SD) HbA1c of 6.99% (0.59) was noted for the 7 patients, representing a mean (SD) change from Baseline of -1.74% (0.78) in HbA1c values. This was a significant (P=0.0011) mean reduction from Baseline values. There were only 5 patients for whom the HbA1c was collected at Week 8 due to the site forgetting to draw blood to obtain these values (minor protocol deviation for patients 01-002 and 01-003) in two patients. A mean (SD) reduction of -1.74 (0.63) was noted for those 5 patients, and this was also a significant (P=0.0034) reduction in HbA1c values.

Insulin Dose (Total, Basal, and Bolus) Change from Baseline

The participants' mean basal dose per day had an non-significant mean (SD) increase of 5.3 (7.6) U/day P=0.0907 from baseline at the end of the PaQ transition phase. The basal dose/rate established during the transition phase remained constant throughout the 12-week PaQ treatment period.

The number of bolus doses administered per day was significantly increased from Baseline during the PaQ transition period (p=0.0301). While slight increases were observed at Weeks 4, 8 and 12 they were not statistically significant. At Week 12, the mean (SD) number of bolus doses per day increased from 3.1 (0.7) at Baseline to 4.3 (1.0) bolus doses administered, a mean (SD) increase of 1.2 (1.7) meal time bolus doses (p=0.0991)

The TDD were not significantly different from Baseline at any study visit. Mean (SD) TDD increased 8.3 (19.6) U from 54.9 (16.2) U at Baseline to a high of 69.7 (31.4) U at Week 4.

Patients with Self-Monitored Blood Glucose Values ≤ 70 mg/dL

Patient 01- 010 accounted for 60% of the episodes. No patient experienced severe hypoglycemia. Seven patients experienced non-severe episodes of hypoglycemia; 3 symptomatic and 7 asymptomatic. The mean (SD) blood glucose level during all episodes was 61.4 (6.71) mg/dL ranging from 36 to 70 mg/dL. There was no difference in the mean (SD) BG value during symptomatic compared to asymptomatic episodes; 60.2 (7.95) mg/dL and 61.6 (6.61) mg/dL, respectively. All events resolved with either no treatment or with the ingestion of food.

Date and Signature of Sponsor representative:

04 - OCT - 2022