

OR30-02: Efficacy and Safety Comparison Between U100 Regular Human Insulin and U100 Rapid Acting Insulin When Delivered by a 24 Hour Wearable Insulin Delivery Device in Type 2 Diabetes

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Introduction: Increasing insulin prices have led to a renewed debate to determine if Rapid Acting Insulin (RAI) analogs offer an advantage over less expensive Regular Human Insulins (RHI). The steep increase in the cost of RAI has led to rationing of insulin or the total discontinuance of therapy by many patients due to cost. For many, RHI provides a more affordable option for insulin therapy when compared to RAI, especially if the limitations of the insulin profile can be overcome by delivering RHI through continuous subcutaneous insulin infusion (CSII) using a wearable insulin delivery device. To our knowledge, no data exists in a type 2 diabetes (T2D) population comparing RAI to RHI when delivered via CSII.

Methods: This 14 week multi-center prospective, randomized parallel, non-inferiority study in a T2D population compared the efficacy and safety of RAI versus RHI when delivered by V-Go[®], a 24-hr wearable patch-like insulin delivery device that provides a preset continuous basal rate of insulin and on-demand bolus dosing. This study was conducted in a real-world practice setting under usual standard of care. Glucose lowering agents were to remain stable unless removal warranted due to documented clinically significant hypoglycemia and the only specific guidance for insulin titration was to down-titrate if blood glucose levels were consistently lower than target range. Patients administering RAI with V-Go were randomized 1:1 to continue RAI or to switch to RHI. Primary endpoint assessed non-inferiority for the between group net difference in HbA1c derived from a mixed model analysis. Between group differences from baseline for insulin total daily dose (TDD) and hypoglycemia (based on 7 point glucose profiles) were evaluated as secondary endpoints.

Results: One hundred thirteen patients (59 RHI and 54 RAI) were evaluated. Baseline characteristics were similar between cohorts. The mean change in HbA1c with RHI was -0.60% from a baseline of 8.41% vs -0.38% from a baseline of 8.33% with RAI (estimated treatment difference [ETD]: -0.22%; 95% confidence interval [CI] -0.67% to 0.22%; non-inferiority margin<0.4% and p=0.007). The mean change in TDD with RHI was 0.8 U/day from a baseline of 61.0 U/day vs 1.8 U/day from a baseline of 61.3 U/day with RAI (ETD: -1.04 U/day; 95% CI: -3.18 U/day to 1.11 U/day; p=0.92). The absolute change in percent of patients reporting hypoglycemia (≤ 70 mg/dL) from pre-randomization to post-randomization was +5.08% with RHI vs + 5.56% with RAI (ETD: -0.48%; 95% CI: -10.6% to 9.1%; p=0.91). Severe hypoglycemia was not reported in either cohort.

Conclusion: Patients with T2D administering RAI with V-Go can safely switch to RHI maintaining similar glycemic control.