NEW INSULIN U300: GLUCOSE CONTROL AND HYPOGLYCAEMIA IN TYPE 2 DIABETES PEOPLE ON BASAL INSULIN AND OADs (EDITION 2)

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Aims: New insulin glargine U300 (Gla-300, 300 U/mL) has even flatter and more prolonged PK and PD profiles than insulin glargine 100 U/mL (Gla-100). EDITION 2 compared the efficacy and safety of Gla-300 vs Gla-100 in people with T2DM using basal insulin and OADs. Methods: In this multicenter, open-label, 6-month study, participants were randomized to Gla-300 or Gla-100 once daily in the evening. Primary endpoint was change in HbA₁c (baseline to month 6). First main secondary efficacy endpoint was participants (%) with ≥1 confirmed or severe (≤3.9 mmol/L) nocturnal hypoglycemia (week 9-month 6). Results: Gla-300 was non-inferior to Gla-100 for change in HbA₁c at month 6 (LS mean change −0.57 [SE 0.09] % and −0.56 [SE 0.09] %; difference −0.01 [95%CI: −0.14-0.12] %). Significantly fewer participants had ≥1 confirmed or severe nocturnal hypoglycemia (week 9-month 6) with Gla-300 vs Gla-100 (87 [21.6%] vs 113 [27.9%]; RR 0.77 [95%CI: 0.61-0.99]; p=0.038). A similar, consistent reduction in confirmed or severe nocturnal hypoglycemia was observed during the first 8 weeks (13.2% vs 24.6%; RR 0.53 [95%CI: 0.38-0.75]) and over the 6-month treatment period (28.3% vs 39.9%; RR 0.71 [95%CI: 0.58-0.87]). Over the 6-month period, fewer participants experienced ≥1 nocturnal hypoglycemic event with Gla-300 vs Gla-100 (30.5% vs 41.6%; RR 0.73 [95%CI: 0.60-0.89]), and any hypoglycemia at any time of day (71.5% vs 79.3%; RR 0.90 [95%CI: 0.84-0.97]). Conclusion: Gla-300 provides similar effective glycemic control, with less confirmed or severe nocturnal hypoglycemia, compared with Gla-100. Study sponsored by Sanofi (NCT01499095).