Impact of Background Antihyperglycaemic Therapy on Insulin Glargine 300 U/mL (Gla-300) vs Insulin Degludec 100 U/mL (IDeg-100) in Insulin-Naïve People with T2DM from the BRIGHT Randomised Study

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BRIGHT (NCT02738151), the first head-to-head trial of Gla-300 and IDeg-100 in T2DM, is a multicentre, open-label, randomised, parallel-group, 24-week actively controlled study, conducted in insulin-naïve participants uncontrolled on current antihyperglycaemic drugs. Participants (mean baseline HbA1c 8.6 %, diabetes duration 10.6 years, BMI 31.5 kg/m2) received Gla-300 (N=466) or IDeg-100 (N=463), titrated to a fasting SMPG of 4.4–5.6 mmol/L, and remained on metformin ± previous antihyperglycaemic therapy. Primary endpoint: change in HbA1c from baseline to week 24; safety endpoints included hypoglycaemia incidence. Here we report HbA1c and hypoglycaemia outcomes by background antihyperglycaemic therapy (no comparisons were performed for metformin as it was received by 92% of participants). Overall distribution of background therapy was: SU/Glinides (65.7%/2.3%), DPP-4i (24.4%), SGLT2i (13.3%), GLP-1 RA (11.9%). Least squares mean differences in HbA1c reduction between Gla-300 and IDeg-100 were similar in those with or without specific background therapies (ranging from −0.09 to −0.03 % across groups with specific background therapies, and from −0.05 to 0.04 % across groups without specific background therapies). There was no evidence of heterogeneity of treatment effect according to use of background antihyperglycaemic therapy on HbA1c reductions (all $p>0.05$). Similarly, there was no evidence of heterogeneity of treatment effect according to use of background antihyperglycaemic therapy on incidence of confirmed (≤3.9 mmol/L or <3.0 mmol/L) or severe hypoglycaemia (all $p>0.05$). In conclusion, background antihyperglycaemic therapies had no impact on the comparable efficacy and hypoglycaemia profiles of Gla-300 and IDeg-100.