Adapting therapy with iGlarLixi versus BIAsp 30 in basal insulin-treated type 2 diabetes: Design and baseline characteristics of the SoliMix randomized controlled trial

**Introduction**

The study involved a clinically relevant population with participants recruited to compare two therapies in people with inadequately controlled type 2 diabetes (T2D) on basal insulin plus one or two oral antihyperglycaemic drugs (OADs). Baseline characteristics did not differ between the two treatment groups. Overall, there were no differences between groups in age, race, gender, body mass index (BMI), duration of diabetes (T2D), or comorbidities.

**Study design**

Prospective, head-to-head, randomized, open-label, blinded-endpoints (RBED) study with titration and dose adjustment of the basal component. The study comprised two parallel treatment arms: iGlarLixi versus BIAsp 30. Week-by-week treatment response was assessed based on weekly changes in key efficacy outcomes. The study involved a clinically relevant population with participants recruited to compare two therapies in people with inadequately controlled type 2 diabetes (T2D) on basal insulin plus one or two oral antihyperglycaemic drugs (OADs).

**Patient reported outcomes**

Patient reported outcomes assessed included quality of life, treatment satisfaction, and treatment-related impact measure (TRIM-D). Treatment-related impact measures were compared with changes in glycemic control at 26 weeks.

**Primary outcome**

The primary outcome was non-inferiority of iGlarLixi versus BIAsp 30 in HbA1c reduction in the first 26 weeks of treatment with a margin of 0.7%.

**Strengths and limitations**

The study was the first trial to directly compare an FRC of basal insulin and GLP-1 RA therapy in people with inadequately controlled T2D on basal insulin plus one or two OADs. The study design and baseline characteristics of SoliMix are described here.

**Conclusion**

The study results support the use of iGlarLixi once daily in basal insulin-treated T2D, as it provides a convenient and effective alternative to the standard of care.