Treating to target in Type 2 diabetes (4-T) study of analogue insulin initiation and titration

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The optimal starting insulin regimen in Type 2 diabetes (T2DM) remains uncertain. 4-T is a three-year, randomised, parallel-group trial in 58 UK and Ireland centres comparing efficacy and safety of three analogue insulin regimens in T2DM patients inadequately controlled on maximally tolerated sulphonylurea and metformin (not glitazone) therapy. 700 insulin-naive participants are being randomised 1:1:1 to additional analogue insulin with long-acting (Levemir) once daily (increasing to twice-daily if needed), prandial rapid acting (NovoRapid) thrice daily, or pre-mixed long and rapid acting (biphasic) twice daily (NovoMix 30). A strict treat-to-target approach aims for plasma glucose levels pre-meal 4.0–5.5 mmol/l, two h post-meal 5.0–7.0 mmol/l and HbA1c< 6.5%. If the HbA1c target is not achieved by one year, sulphonylurea is replaced by a pre-specified second insulin formulation. In 437 patients randomised to date, median (IQR) starting insulin dose (determined from fasting plasma glucose, body weight and gender using a prescriptive algorithm) is 18 (10 to 27), ranging from 2 to 76 units, with no major hypoglycaemic episodes (requiring assistance) reported in the subsequent fortnight.

Conclusion: T2DM patients inadequately controlled on sulphonylurea and metformin therapy can have analogue insulin added using individually calculated starting doses without apparent risk of major hypoglycaemic episodes.