

inadequately controlled on oral antidiabetic drug (OADs)] and DUAL II (IDegLira vs IDeg in patients inadequately controlled on basal insulin and OADs), in which IDegLira was initiated at 10 and 16 dose steps, respectively. One dose step consists of one unit of IDeg and 0.036 mg of Lira. We compared the proportion of subjects experiencing GI side effects, often associated with GLP-1RA therapy during the first 12 weeks of treatment.

**Results:** There was no statistically significant difference between the odds of experiencing GI side effects for subjects on IDegLira vs pooled non-GLP-1RA therapy at weeks 4, 8, 12, or during the entire trial period (odds ratios: DUAL IV 1.0, 2.0, 0.4, 0.9; DUAL II 2.0, 1.1, 1.1, 2.0, respectively).

**Conclusions:** A similar proportion of subjects treated with IDegLira experienced GI side effects vs IDeg or placebo. This may be explained by the slow and steady titration of IDegLira, leading to improved tolerability without losing glycaemic control.

## P114

### Once-daily liraglutide vs lixisenatide as add-on to metformin in Type 2 diabetes: a 26 week randomised controlled clinical trial

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**Aims:** To compare the efficacy and safety of liraglutide (lira) vs lixisenatide (lixi) as add-on to metformin (MET) in patients with Type 2 diabetes not achieving adequate glycaemic control on MET alone.

**Methods:** In this 26 week, parallel-group, open-label trial (NCT01973231), patients [age  $\geq 18$  years, HbA1c 7.5–10.5% (58–91 mmol/mol), body mass index (BMI)  $\geq 20$  kg/m<sup>2</sup>] were randomised 1:1 to lira 1.8 mg or lixi 20  $\mu$ g as add-on to MET. Lira was administered once daily (OD) at any time of the day. Lixi OD was administered within an hour prior to the morning or evening meal.

**Results:** 404 patients (age 56 years, BMI 35 kg/m<sup>2</sup>, HbA1c 8.4% (68 mmol/mol), Type 2 diabetes duration 6.4 years) were randomised. At week 26, lira was associated with greater reduction in HbA1c (estimated treatment difference  $-0.62\%$ , 95% CI  $-0.80$  to  $-0.44$ ;  $p < 0.0001$ ), more patients reaching HbA1c goals of  $<7\%$  and  $\leq 6.5\%$  and enhanced HOMA-B function compared with lixi. Greater reductions in fasting plasma glucose and mean nine-point self-measured plasma glucose were observed with lira; with lixi there were smaller postprandial glucose increments for the meal following injection. Lira and lixi showed similar decreases in weight ( $-4.3$  kg and  $-3.7$  kg, respectively; statistically non-significant) and blood pressure (BP), low incidence of hypoglycaemia and comparable adverse events (AEs) (nausea 21.8% and 21.8%, respectively; diarrhoea 12.4% and 9.9%, respectively).

**Conclusions:** Lira was more efficacious than lixi as add-on to MET in achieving glycaemic control and improving HOMA-B function. Treatments showed similar body weight and BP reductions, low risk of hypoglycaemia and comparable gastrointestinal AE profiles.

## P115

### Using a low energy formula diet in obese patients with long-standing insulin-treated Type 2 diabetes produces significantly greater weight loss, improvement in glucose control and insulin reductions compared to gold standard clinical care over a 12 week period

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**Introduction:** Insulin is the most potent therapy for glycaemic control in the management of Type 2 diabetes, but its use is associated with weight gain. Acute energy restriction may have a role in weight loss and reduction in insulin requirements.

**Aims:** To investigate the short-term (12 week) effects of a low energy formula diet (LED) compared with gold standard clinical care (GSC) on weight loss, glycaemic control and reduction in insulin dose in patients with long-standing insulin-treated Type 2 diabetes.

**Methods:** Twenty obese patients with Type 2 diabetes treated with insulin (mean age  $55.8 \pm 9.1$  years, weight  $100.1 \pm 10.4$  kg, diabetes duration  $13.6 \pm 7.2$  years, duration on insulin  $4.7 \pm 3.0$  years, insulin dosage  $63.5 \pm 37.3$  units) were randomised into either LED (808–836 kcal/day) or GSC (600 kcal deficit diet) for 12 weeks ( $n = 10$ , each group). Both received additional behaviour change and physical activity advice. Results shown are mean  $\pm$  SD.

**Results:** Weight loss was greater using an LED compared to GSC ( $9.8 \pm 4$  kg vs  $2.2 \pm 2.2$  kg;  $p < 0.0001$ ). Percentage total insulin dose fell in both groups ( $-75.7\%$  LED,  $-46.1\%$  GSC;  $p = 0.0001$ ). Four patients using an LED discontinued insulin compared with none on GSC. HbA1c was reduced by 11.3 mmol/mol (1.0%) following LED ( $p = 0.009$ ) and by 7.0 mmol/mol (0.63%) following GSC ( $p = 0.09$ ). Fat mass was reduced in both LED and GSC ( $p = 0.011$  and  $p = 0.004$ , respectively) with a greater reduction in the LED group (3.67 kg;  $p = 0.023$ ). Lean mass loss was not significantly different in both LED and GSC ( $p = 0.053$  and  $p = 0.398$ ).

**Conclusions:** Using a LED for 12 weeks produces significantly greater weight loss, reduction in insulin dosage and improvement in HbA1c within long-standing insulin-treated Type 2 diabetes patients compared with gold standard clinical care.