Buse 2011

NCT00765817

1 Treatments

Studied treatment  twice-daily 10 µg exenatide injections

Control treatment  placebo (on top insulin glargine)

Concomittant treatments  insulin glargine alone or in combination with metformin or pioglitazone or both

Age (year)  59 y

Add-on to  -

women (%)  42.9%

treated with MET, %  70.2%

treated with MET+SU, %  -

treated with SU alone, %  -

weight (kg)  94.5

Weight, kg  -

FPG, mmol/L  -

2 Patients

Patients  Adults with type 2 diabetes and an HbA1c level of 7.1% to 10.5% who were receiving insulin glargine alone or in combination with metformin or pioglitazone (or both agents)

Inclusion criteria  at least 18 years of age; type 2 diabetes; receiving insulin glargine at a minimum of 20 U/d without any other insulin, alone or in combination with a stable dose of metformin or pioglitazone (or both agents) for at least 3 months; HbA1c level of 7.1% to 10.5%, body mass index of 45 kg/m2 or less, and stable body weight (less than 5% change over 3 months)

Exclusion criteria  clinically significant hematologic, oncologic, renal, cardiac, hepatic, or gastrointestinal disease; in a weight-loss program in the 3 months before the study; systemic glucocorticoid therapy in the 8 weeks before the study; more than 1 episode of major hypoglycemia in the 6 months before the study; irregular sleep–wake cycle; or history of pancreatitis

Duration of diabetes (year)  -
BMI 33.5

Systolic blood pressure (mm Hg) 129.1

Diastolic blood pressure (mm Hg) 75.19

FPG, mmol/L 8.09

prestudy OAD monotherapy -

prestudy OAD combination therapy -

3 Methods

Blinding double-blind

Design Parallel groups

Centers 59

Geographical area Greece, Israel, Mexico, United Kingdom, USA

Sizes 138/123

HbA1c (%) 8.4%

Fasting C-peptide (nmol/L) -
4 Results

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>T1</th>
<th>T0</th>
<th>d</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>stroke</td>
<td>-/138</td>
<td>-/123</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>CV deaths</td>
<td>-/138</td>
<td>-/123</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>HbA1c inférieur à 6.5% minor hypoclycaemia</td>
<td>-/138</td>
<td>-/123</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>nocturnal hypoglycaemia</td>
<td>-/138</td>
<td>-/123</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>all hypoglycaemia</td>
<td>-/138</td>
<td>-/123</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>HbA1c inf a 7CV events</td>
<td>-/138</td>
<td>-/123</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>death</td>
<td>0/137</td>
<td>1/122</td>
<td>0.30</td>
<td>[0.01; 7.36]</td>
</tr>
<tr>
<td>treatment-emergent adverse events (TEAEs)</td>
<td>109/137</td>
<td>86/122</td>
<td>1.13</td>
<td>[0.64; 2.00]</td>
</tr>
<tr>
<td>serious adverse events</td>
<td>-/138</td>
<td>-/123</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>severe adverse events</td>
<td>8/137</td>
<td>11/122</td>
<td>0.66</td>
<td>[0.26; 1.66]</td>
</tr>
<tr>
<td>ant hypoglycemia</td>
<td>-/138</td>
<td>-/123</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>severe hypoglycemia</td>
<td>0/137</td>
<td>1/122</td>
<td>0.30</td>
<td>[0.01; 7.36]</td>
</tr>
<tr>
<td>nausea</td>
<td>56/137</td>
<td>10/122</td>
<td>4.79</td>
<td>[2.34; 9.83]</td>
</tr>
<tr>
<td>vomiting</td>
<td>25/137</td>
<td>5/122</td>
<td>4.13</td>
<td>[1.59; 10.75]</td>
</tr>
<tr>
<td>diarrhea</td>
<td>25/137</td>
<td>10/122</td>
<td>2.16</td>
<td>[1.01; 4.65]</td>
</tr>
</tbody>
</table>

5 References