Barnett 2007

NCT00099619

1 Treatments

Studied treatment  Exenatide 20 µg daily
subcutaneous injection, 10 µg/day for 4 weeks then 20 µg/day for 12 weeks, administered twice daily

Control treatment  Insulin
titrated to FBG <= 5.6 mmol/l, initiated at 10 IU and increased weekly, four times daily

Concomittant treatments  sulphonylureas or metformin

Age (year)  55

Add-on to  SU/Met

women (%)  51%

treated with MET, %  55.1%
treated with MET+SU, %  0%
treated with SU alone, %  44.9%

weight (kg)  85

Weight, kg  85 kg

FPG, mmol/L  12 mmol/L

2 Patients

Patients  patients with type 2 diabetes

Inclusion criteria  Type 2 diabetes, equal to or more than 30 years of age, receiving treatment with either a stable dose of immediate- or extended-release MET equal to or greater than 1500 mg/day or an optimally effective dose of SFU for 3 months, HbA1c level equal to, or more than, 7.1% and equal to, or less than, 11%, BMI more than 25 kg/m2 and less than 40 kg/m2, stable body weight (not varying by more than 10% for at least 3 months prior to screening)

Exclusion criteria  -

Duration of diabetes (year)  7.4 y

BMI  31.1

Systolic blood pressure (mm Hg)  -
Diastolic blood pressure (mm Hg) -

FPG, mmol/L -

prestudy OAD monotherapy -

prestudy OAD combination therapy -

3 Methods

Blinding open

Design Cross over

Centers 26

Geographical area Australia, Greece, Hungary, Italy, Mexico, and Poland

Sizes 136/127

HbA1c (%) 8.9

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>
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<tbody>
<tr>
<td>stroke</td>
<td>-/136</td>
<td>-/127</td>
<td>NA</td>
<td>-</td>
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<tr>
<td>CV deaths</td>
<td>-/136</td>
<td>-/127</td>
<td>NA</td>
<td>-</td>
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<tr>
<td>HbA1c inférieur à 6.5</td>
<td>-/136</td>
<td>-/127</td>
<td>NA</td>
<td>-</td>
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<tr>
<td>nocturnal hypoglycaemia</td>
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<td>-/127</td>
<td>NA</td>
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<tr>
<td>all hypoglycaemia</td>
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<td>-/127</td>
<td>NA</td>
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<td>HbA1c inf a 7CV events</td>
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<td>0/127</td>
<td>0,93</td>
<td>[0,02; 47,42]</td>
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<tr>
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<td>0/127</td>
<td>0,93</td>
<td>[0,02; 47,42]</td>
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<td>treatment-emergent adverse events (TEAEs)</td>
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<td>-/127</td>
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<tr>
<td>serious adverse events</td>
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<td>-/127</td>
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<tr>
<td>severe adverse events</td>
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<td>-/127</td>
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<td>ant hypoglycemia</td>
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<td>32/127</td>
<td>0,59</td>
<td>[0,32; 1,09]</td>
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<td>0,13</td>
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<td>4/127</td>
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<td>1,20</td>
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5 References

10.1016/j.clinthera.2007.11.006