LEADER 2016

NCT01179048

1 Treatments

Studied treatment  Maximum dose of 1.8 mg liraglutide, injected subcutaneously once daily

Control treatment  placebo

Concomittant treatments  standard care

Age (year)  -

Add-on to  -

women (%)  -

treated with MET, %  -

treated with MET+SU, %  -

treated with SU alone, %  -

weight (kg)  -

Weight, kg  -

FPG, mmol/L  -

HbA1c at the end of study  -

2 Patients

Patients  subjects with type 2 diabetes

Inclusion criteria  1) Type 2 diabetes; 2) Age min. 50 years at screening and concomitant cardiovascular, cerebrovascular or periphera vascular disease or chronic renal failure or chronic heart failure OR age min. 60 years at screening and other specified risk factors of vascular disease; 3) HbA1c: 7.0% or above; 4) Anti-diabetic drug naive or treated with one or more oral anti-diabetic drugs (OADs) or treated with human NPH insulin or long-acting insulin analogue, alone or in combination with OAD(s);

Exclusion criteria  1) Type 1 diabetes; 2) Use of a glucagon-like peptide-1 (GLP-1) receptor agonist (exenatide, liraglutide or other) or pramlintide or any dipeptidyl peptidase 4 (DPP-4) inhibitor within the 3 months prior to screening (trial start); 3) Use of insulin other than human NPH insulin or long-acting insulin analogue within the 3 months prior to screening (trial start). Short-term use of other insulin during this period in connection with intercurrent illness is allowed at the discretion of the Investigors (physicians);
Duration of diabetes (year) -

BMI -

Systolic blood pressure (mm Hg) -

Diastolic blood pressure (mm Hg) -

FPG, mmol/L -

prestudy OAD monotherapy -

prestudy OAD combination therapy -

3 Methods

Blinding double-blind

Design -

Centers -

Geographical area Africa, Asia, Europe, North and South America

Sizes 4668/4672

HbA1c (%) -

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>Microvascular event</td>
<td>355/4668</td>
<td>416/4672</td>
<td>0.85</td>
<td>[0.74; 0.99]</td>
</tr>
<tr>
<td>fatal and non fatal MI</td>
<td>292/4668</td>
<td>339/4672</td>
<td>0.86</td>
<td>[0.73; 1.01]</td>
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<tr>
<td>Hospitalization for heart failure</td>
<td>218/4668</td>
<td>248/4672</td>
<td>0.88</td>
<td>[0.73; 1.06]</td>
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<tr>
<td>fatal and non fatal stroke</td>
<td>173/4668</td>
<td>199/4672</td>
<td>0.87</td>
<td>[0.71; 1.07]</td>
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<tr>
<td>CV events</td>
<td>608/4668</td>
<td>694/4672</td>
<td>0.88</td>
<td>[0.78; 0.99]</td>
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<tr>
<td>Retinopathy</td>
<td>106/4668</td>
<td>92/4672</td>
<td>1.15</td>
<td>[0.87; 1.53]</td>
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<td>CV death</td>
<td>219/4668</td>
<td>278/4672</td>
<td>0.79</td>
<td>[0.66; 0.95]</td>
</tr>
<tr>
<td>Nephropathy</td>
<td>268/4668</td>
<td>337/4672</td>
<td>0.80</td>
<td>[0.67; 0.94]</td>
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<tr>
<td>all causes death</td>
<td>381/4668</td>
<td>447/4672</td>
<td>0.85</td>
<td>[0.74; 0.98]</td>
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</table>
5 References


