LEAD-1 SU (1.8 mg vs placebo) 2009

NCT00318422

1 Treatments

Studied treatment  Liraglutide 1.8 mg daily

Control treatment  Placebo on-top of sulphonylureas

Concomittant treatments  glimepiride (2– 4 mg/day)

Age (year)  53%

Add-on to  8.4

women (%)  80.6 kg

treated with MET, %  -

treated with MET+SU, %  -

treated with SU alone, %  -

weight (kg)  -

Weight, kg  -

FPG, mmol/L  SU

2 Patients

Patients  patients with type 2 diabetes

Inclusion criteria  1) Type 2 diabetes; 2) Treatment with oral anti-diabetic drugs for at least 3 months; 3) HbA1c: 7.0-11.0 % (both incl.) in subjects on OAD monotherapy. 7.0-10.0 % (both incl.) in subjects on OAD combination therapy; 4) Body Mass Index (BMI) less than or equal to 45.0 kg/m2.;

Exclusion criteria  1) Treatment with insulin within the last three months; 2) Treatment with any drug that could interfere with the glucose level; 3) Any serious medical condition; 4) Females who are pregnant, have the intention of becoming pregnant or are breastfeeding;

Duration of diabetes (year)  133

BMI  56 y

Systolic blood pressure (mm Hg)  -

Diastolic blood pressure (mm Hg)  9.9 mmol/L
LEAD-1 SU (1.8 mg vs placebo), 2009

FPG, mmol/L 68%

prestudy OAD monotherapy 30.0

prestudy OAD combination therapy 32%

3 Methods

Blinding double-blind

Design Parallel groups

Centers 116

Geographical area 21 countries

Sizes 234/114

HbA1c (%) -

Fasting C-peptide (nmol/L) 7.9 y

4 Results

<table>
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<tr>
<th>Endpoint</th>
<th>T1</th>
<th>T0</th>
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<td>stroke</td>
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<td>CV deaths</td>
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5 References

Marre M, Shaw J, Brändle M, Bebakar WM, Kamaruddin NA, Strand J, Zdravkovic M, Le Thi TD, Colagiuri S. Liraglutide, a once-daily human GLP-1 analogue, added to a sulphonylurea over 26 weeks produces greater improvements in glycaemic and weight control compared with adding rosiglitazone or placebo in subjects with Type 2 diabetes (LEAD-1 SU). Diabet Med 2009;26:268-78 [19317822] 10.1111/j.1464-5491.2009.02666.x