ROADMAP 2010

NCT00185159

1 Treatments

Studied treatment  olmesartan at 40 mg/day

Control treatment  placebo

Concomittant treatments  antihypertensive drugs (except angiotensin-converting–enzyme inhibitors or ARBs) used as needed to lower blood pressure to less than 130/80 mm Hg

2 Patients

Patients  patients with diabetes and at least one additional cardiovascular risk factor, but no evidence of renal dysfunction

Inclusion criteria  diabetes mellitus type 2, defined as fasting blood glucose of greater than or equal to 126 mg/dL; at least one of the following cardiovascular risk factors: total cholesterol greater than 200 mg/dL or statin treatment, high density lipoprotein (HDL) less than 40 mg/dL, triglycerides greater than 150 mg/dL and less than 400 mg/dL, blood pressure greater than or equal to 130/80 mmHg, body mass index (BMI) greater than 28 kg/m2, waist circumference greater than 102 cm for men and greater than 88 cm for women, smoking of more than 5 cigarettes a day; normoalbuminuria at screening

Exclusion criteria  -

3 Methods

Blinding  double-blind

Design  Parallel groups

Centers  262

Geographical area  Europe (19 countries)

Sizes  2232/2215
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>non fatal stroke</td>
<td>14/2232</td>
<td>8/2215</td>
<td>1.74</td>
<td>[0.73; 4.15]</td>
</tr>
<tr>
<td>non fatal MI</td>
<td>17/2232</td>
<td>26/2215</td>
<td>0.65</td>
<td>[0.35; 1.20]</td>
</tr>
<tr>
<td>onset of microalbuminuria</td>
<td>-/2160</td>
<td>-/2139</td>
<td>0.77</td>
<td>[0.63; 0.94]</td>
</tr>
<tr>
<td>CV death</td>
<td>15/2232</td>
<td>3/2215</td>
<td>4.96</td>
<td>[1.43; 17.16]</td>
</tr>
<tr>
<td>CV events</td>
<td>63/2232</td>
<td>71/2215</td>
<td>0.88</td>
<td>[0.62; 1.24]</td>
</tr>
<tr>
<td>all cause death</td>
<td>26/2232</td>
<td>15/2215</td>
<td>1.72</td>
<td>[0.91; 3.26]</td>
</tr>
</tbody>
</table>

5 References
