NAVIGATOR nateglinide 2010

NCT00097786

1 Treatments

Studied treatment nateglinide 60mg 3 times daily
Nateglinide was initially dispensed at a dose of 30 mg, with an increase to the full dose of 60 mg after 2 weeks

Control treatment placebo

Concomittant treatments lifestyle modification

Women (%) 51%

Age (mean), years 63.7 y

2 Patients

Patients subjects with impaired glucose tolerance and either CV disease or CV risk factors

Inclusion criteria impaired glucose tolerance; fasting plasma glucose level of at least 95 mg per deciliter (5.3 mmol per liter) but less than 126 mg per deciliter (7.0 mmol per liter); and one or more cardiovascular risk factors (if 55 years of age or older) or known cardiovascular disease (if 50 years of age or older)

Exclusion criteria laboratory abnormalities or conditions that could interfere with assessment of the safety or efficacy of a study drug; use of an ACE inhibitor or ARB for the treatment of hypertension (although ACE inhibitors were allowed for other indications); use of an antidiabetic medication within the previous 5 years

Weight (kg) 83.6 kg

Body-mass index (kg/m2) 30.5

Waist circumference (cm) 101cm (M 104/ F 98)

obesity -

Family history of diabetes mellitus (%) 38%

Definitions of impaired glucose tolerance and type 2 diabetes -

3 Methods

Blinding double-blind

Design Factorial plan

Centers 806
Geographical area  40 countries

Sizes  4645/4661

fasting plasma glucose (mmol/L)  6.1 mmol/l

2-h plasma glucose (mmol/L)  9.2 mmol/l

Dyslipidaemia  44.7%

2hPG (>9.4–11.0 mmol/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>hospitalization for heart failure</td>
<td>85/4645</td>
<td>100/4661</td>
<td>0.85</td>
<td>[0.64; 1.14]</td>
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<tr>
<td>death</td>
<td>310/4645</td>
<td>312/4661</td>
<td>1.00</td>
<td>[0.85; 1.17]</td>
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<tr>
<td>CV death</td>
<td>126/4645</td>
<td>118/4661</td>
<td>1.07</td>
<td>[0.83; 1.38]</td>
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<tr>
<td>CV death, MI, stroke</td>
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<td>-/4661</td>
<td>NA</td>
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<tr>
<td>diabetes</td>
<td>1674/4645</td>
<td>1580/4661</td>
<td>1.06</td>
<td>[0.98; 1.16]</td>
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<tr>
<td>fatal and non fatal MI</td>
<td>135/4645</td>
<td>143/4661</td>
<td>0.95</td>
<td>[0.75; 1.20]</td>
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<td>-/4661</td>
<td>NA</td>
<td>-</td>
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<tr>
<td>fatal and non fatal stroke</td>
<td>111/4645</td>
<td>126/4661</td>
<td>0.88</td>
<td>[0.68; 1.14]</td>
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<td>cardiovasculaire events</td>
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<td>387/4661</td>
<td>0.95</td>
<td>[0.82; 1.10]</td>
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5 References