NAVIGATOR valsartan 2010

NCT00097786

1 Treatments

Studied treatment  valsartan up to 160 mg daily

Control treatment  placebo

Concomittant treatments  -

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)  101 cm (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** 4631/4675

**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>91/4631</td>
<td>94/4675</td>
<td>0.98</td>
<td>[0.73; 1.31]</td>
</tr>
<tr>
<td>death</td>
<td>295/4631</td>
<td>327/4675</td>
<td>0.91</td>
<td>[0.77; 1.07]</td>
</tr>
<tr>
<td>CV death</td>
<td>128/4631</td>
<td>116/4675</td>
<td>1.11</td>
<td>[0.86; 1.44]</td>
</tr>
<tr>
<td>CV death, MI, stroke</td>
<td>-/4631</td>
<td>-/4675</td>
<td>NA</td>
<td>-</td>
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<tr>
<td>diabetes</td>
<td>1532/4631</td>
<td>1722/4675</td>
<td>0.90</td>
<td>[0.82; 0.98]</td>
</tr>
<tr>
<td>fatal and non fatal MI</td>
<td>138/4631</td>
<td>140/4675</td>
<td>1.00</td>
<td>[0.78; 1.26]</td>
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<tr>
<td>normoglycemia</td>
<td>-/4631</td>
<td>-/4675</td>
<td>NA</td>
<td>-</td>
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<tr>
<td>fatal and non fatal stroke</td>
<td>105/4631</td>
<td>132/4675</td>
<td>0.80</td>
<td>[0.62; 1.04]</td>
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<tr>
<td>cardiovasculaire events</td>
<td>672/4631</td>
<td>693/4675</td>
<td>0.98</td>
<td>[0.87; 1.10]</td>
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</table>

### 5 References
