AIM-HIGH 2011

NCT00120289

1 Treatments

Studied treatment  high-dose, extended-release niacin in gradually increasing doses up to 2000 mg daily (+ simvastatin)
high-dose extended-release niacin (Niaspan) given in addition to statin therapy

Control treatment  placebo

Concomittant treatments  simvastatin (and ezetimibe, in order to maintain LDL-cholesterol levels at the target range between 40 and 80 mg/dL)

Male (%)  -
Age (years)  -

2 Patients

Patients  patients with a history of cardiovascular disease, high triglycerides, and low levels of HDL cholesterol

Inclusion criteria  men and women; >=45 years old; with established vascular disease and atherogenic dyslipidemia; established vascular disease defined as one or more of the following: (1) documented coronary artery disease (CAD); (2) documented cerebrovascular or carotid disease; (3) documented symptomatic peripheral arterial disease (PAD) Atherogenic dyslipidemia defined as: (1) LDL-C of less than or equal to 160 mg/dL (4.1 mmol/L); (2) HDL-C of less than or equal to 40 mg/dL (1.0 mmol/L) for men or less than or equal to 50 mg/dL (1.3 mmol/L) for women; (3) TG greater than or equal to 150 mg/dL (1.7 mmol/L) and less than or equal to 400 mg/dL (4.5 mmol/L) For patients entering the trial on a statin: (1) the upper limit for LDL-C is adjusted according to the specific statin and statin dose; (2) HDL-C of less than or equal to 42 mg/dL (1.1 mmol/L) for men or less than or equal to 53 mg/dL (1.4 mmol/L) for women; (3) TG greater than or equal to 125 mg/dL (1.4 mmol/L) and less than or equal to 400 mg/DL (4.5 mmol/L)

Exclusion criteria  -
Diabetes (%)  -
History of CHD  -

3 Methods

Blinding  double blind
Design  Parallel groups
Centers  -
**Geographical area**  US, Canada

**Sizes**  1718/1691

**4 Results**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>T1</th>
<th>T0</th>
<th>d</th>
<th>95% CI</th>
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<tbody>
<tr>
<td>coronary death</td>
<td>-/1718</td>
<td>-/1691</td>
<td>NA</td>
<td>-</td>
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<tr>
<td>all-cause death</td>
<td>-/1718</td>
<td>-/1691</td>
<td>NA</td>
<td>-</td>
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<tr>
<td>HDL</td>
<td>-/1718</td>
<td>-/1691</td>
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<td>stroke</td>
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<td>15/1696</td>
<td>1,78</td>
<td>[0,94; 3,35]</td>
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<td>cardiovascular deaths</td>
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<td>-/1691</td>
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**5 References**