HOPE-2 (Lonn) 2006

NCT00106886

A randomised clinical trial investigating the effect of folic acid, vit B12 and vit B6 versus placebo in patients 55 years of age or older who had vascular disease or diabetes and additional risk factors for atherosclerosis

1 Treatments

- **Studied treatment**: folic acid, 2.5 mg, vitamin B6, 50 mg and vitamin B12, 1 mg
- **Control treatment**: placebo
- **Concomittant treatments**: -

2 Patients

- **Patients**: patients 55 years of age or older who had vascular disease or diabetes and additional risk factors for atherosclerosis
- **Inclusion criteria**: -
- **Exclusion criteria**: current use of vitamin supplements with a high content of folic acid and vitamins B6 and B12; presence of other illnesses or conditions expected to limit compliance and/or impact on patients’ ability to complete the study

3 Methods

- **Blinding**: double blind
- **Design**: Parallel groups
- **Centers**: 145
- **Geographical area**: 13 countries
- **Sample size**: 5522 (2758 / 2764)
- **ArretTrt1**: -
- **ArretTrt0**: -
- **PeriodInclusion**: Jan 2000 - Dec 2000
- **Hypothese**: Superiority
## 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 MI</td>
<td>-/307</td>
<td>-/312</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>stroke (fatal non fatal)</td>
<td>111/2758</td>
<td>147/2764</td>
<td>0,76</td>
<td>[0,59; 0,97]</td>
</tr>
<tr>
<td>cardiovascular event (fatal and non fatal)</td>
<td>519/2758</td>
<td>547/2764</td>
<td>0,95</td>
<td>[0,83; 1,09]</td>
</tr>
<tr>
<td>Incident cancer</td>
<td>358/2758</td>
<td>340/2764</td>
<td>1,06</td>
<td>[0,90; 1,24]</td>
</tr>
<tr>
<td>Death from any cause</td>
<td>470/2758</td>
<td>475/2764</td>
<td>0,99</td>
<td>[0,86; 1,14]</td>
</tr>
<tr>
<td>Death due to cancer</td>
<td>94/2758</td>
<td>95/2764</td>
<td>0,99</td>
<td>[0,74; 1,33]</td>
</tr>
<tr>
<td>Death from cardiovascular causes</td>
<td>276/2758</td>
<td>291/2764</td>
<td>0,95</td>
<td>[0,80; 1,13]</td>
</tr>
<tr>
<td>Death from CHD</td>
<td>-/307</td>
<td>-/312</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>341/2758</td>
<td>349/2764</td>
<td>0,98</td>
<td>[0,83; 1,15]</td>
</tr>
</tbody>
</table>

## 5 References


## 6 Comments