The effect of pravastatin on coronary events after myocardial infarction in patients with average cholesterol levels (CARE)

Study Type: POEM, Secondary prevention

Purpose: Does lowering cholesterol in patients with average LDL levels of 115 to 174 prevent coronary events in patients after an MI?

Study Duration: mean 5 year follow-up

Trial Design: randomized placebo-controlled trial; secondary prevention trial; multicenter (13 centers in Canada and 67 centers in USA)

Drug: Pravastatin 40 mg QD vs matching placebo

Patients: 4159 patients, 92% white, males (86%), females (14%), mean age of 59 yrs, baseline lipids: TC 209 mg/dl, LDL 139 mg/dl, HDL 39 mg/dl, HTN (43%), smokers (21%), DM (15%)

Inclusion: men and postmenopausal women, 21 to 75 yrs, TC < 240 mg/dl, LDL 115-174 mg/dl, Hx of MI 3-20 months previously


Primary Outcome: death from CHD or nonfatal MI

Are the results valid?
Randomized? yes
Blinded? yes
Study/control groups similar at start? yes
Equal treatment of groups? yes
Proper accounting at end? yes

What are the results?

<table>
<thead>
<tr>
<th>Primary Outcome</th>
<th>Placebo</th>
<th>Pravastatin</th>
<th>p-value</th>
<th>RRR</th>
<th>ARR</th>
<th>NNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death from CHD or nonfatal MI</td>
<td>13.2%</td>
<td>10.2%</td>
<td>.003</td>
<td>24%</td>
<td>3%</td>
<td>33</td>
</tr>
<tr>
<td>Death from CHD</td>
<td>5.7%</td>
<td>4.6%</td>
<td>NS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonfatal MI</td>
<td>8.3%</td>
<td>6.5%</td>
<td>.02</td>
<td>23%</td>
<td>1.8%</td>
<td>56</td>
</tr>
<tr>
<td>Fatal MI</td>
<td>1.8%</td>
<td>1.2%</td>
<td>NS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CABG</td>
<td>10%</td>
<td>7.5%</td>
<td>.005</td>
<td>26%</td>
<td>2.5%</td>
<td>40</td>
</tr>
<tr>
<td>PTCA</td>
<td>10.5%</td>
<td>8.3%</td>
<td>.01</td>
<td>23%</td>
<td>2.2%</td>
<td>45</td>
</tr>
<tr>
<td>Stoke</td>
<td>3.8%</td>
<td>2.6%</td>
<td>.03</td>
<td>31%</td>
<td>1.2%</td>
<td>83</td>
</tr>
<tr>
<td>All-cause death</td>
<td>9.4%</td>
<td>8.6%</td>
<td>NS</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Will the results help me?
1. Those with the highest LDL level got the best benefit from treatment.
2. Lowering LDL maybe beneficial in women, > 60 yrs, smokers, and LDL > 150 mg/dl after MI.
3. Those > 60 years of age, who have hypertension and are smokers got the best benefit from treatment.
4. Average lipid values at endpoint in treatment group were TC 167 mg/dl, LDL 97 mg/dl, HDL 41 mg/dl.
5. Increased incidence of breast cancer in pravastatin group (P = .002, ARI = 0.6%, NNH = 166)

Conclusion: For every 1000 white male patients with an average LDL cholesterol level of 115-174, 30 deaths from coronary heart disease or nonfatal MI’s would be prevented, 12 strokes and 18 nonfatal MI’s prevented, but no change in all-cause mortality. Five years of therapy for 1000 patients would be $7 million dollars.

June 2010 - Of course the price of pravastatin has dropped since it is generic and often on discount drug plans.

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