

Clinical Update

Industry slams B vitamins trial

A clinical trial that concluded B vitamins do not reduce the risk of cardiovascular (CV) events or death among patients with coronary heart disease has been criticized by industry for being poorly designed

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The study analysed 3096 patients with heart problems in two Norwegian hospitals over a seven-year period ending in 2006. It concluded there was no statistical difference in CV events and death between the groups taking the B vitamins and those on placebo.

Daniel Fabricant, PhD, vice president of scientific and regulatory affairs at the trade group Natural Products Association said the *“the study’s exclusion criteria leave much to be desired.”*

“For example, over 78 percent of the subjects were concomitantly taking beta blockers, and over 88 percent were taking statins amongst other medical interventions and treatments,” he said. *“We have no way of knowing from reading the study whether these interventions were continued through the lifecycle of the study, which could significantly influence the outcomes. The researchers mention adherence to the ‘study medication’ (the B-vitamins) but not to other treatments; additionally the authors did not control food intake for folic acid, B-6 or B-12.”*

The veracity of homocysteine as a CV disease marker across all population segments was also questioned. While the marker may be more relevant for older populations, it did not necessarily apply to younger demographics.

“We know for certain is that there are significant populations of older people with CVD who have moderately low concentrations of serum vitamin B12; similarly, there are also populations of the elderly with CVD that have elevated concentrations of plasma HCY.”

“Applying some degree of common sense, there is a plausible link that needs to be investigated further. It is important, however that these findings not become generalized, applied and reported to be related to a healthy population that may be responsibly supplementing with B vitamins and the preventative benefits they may derive.”

Fabricant added: *“A study such as this ... is in no way conclusive and should not be represented as such, or be used in any way to stop those who may currently benefit from taking B-vitamins from continuing their regimens. The overwhelming body of research shows that poor nutrition is much more of a health risk than using optimal levels of B-vitamin supplementation in a balanced diet, exercise and health regimen.”*

Speaking more broadly, Andrew Shao, PhD, vice president of scientific and regulatory affairs at the Washington DC-based Council for Responsible Nutrition (CRN), said the results vindicated the manner in which B and other vitamins should be used.

“This study, like other similarly designed studies, fails to answer the question of whether B vitamin supplementation, over the long-term, can help reduce the risk of cardiovascular disease in a population that is healthy at baseline,” Shao said.

Source: www.nutraingredients.com