IL-1 Heart Health

Double-Blind, Placebo-Controlled trial to

Evaluate the Effect of Nutilite IL1 Heart

Health Dietary Supplement on IL-1 Gene

Expression, IL-1 Production, and C-Reactive

Protein in Healthy Human Subjects

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Clinical Test Centers:

Alticor Inc., Access Business Group LLC, Southbay Pharma Research, East Coast Clinical Research,

Omega Medical Research, Providence Clinical Research, and Sall Research Medical Center

References:

1. Berger, P., et al. (2002). C-reactive protein levels are influenced by common Il-1 gene variations. *Cytokine, 17*, 171-174.

2. Duff, G. (2000). Genetic variation in cytokines and relevance to inflammation and disease. In F. Balkwill (Ed.), *The Cytokine Network: Frontiers in Molecular Biology, 25*, (pp. 152-173). United Kingdom: Oxford University Press.

3. Pearson, T. A., et al. (2003). Markers of inflammation and cardiovascular disease: application to clinical and public health practice: A statement for healthcare professionals from the Centers for Disease Control and Prevention and the American Heart Association. *Circulation, 107*, 499-511.
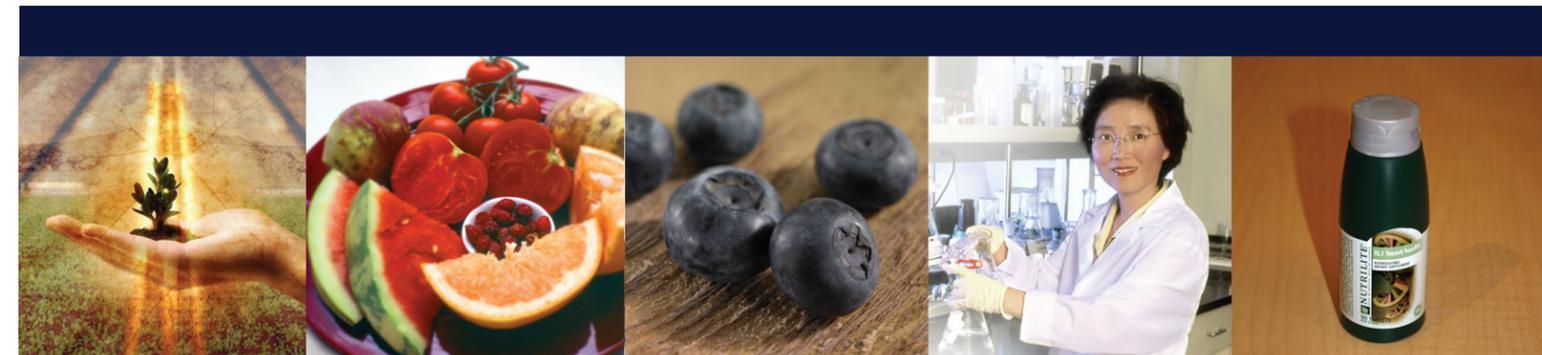
NUTRILITE
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The impact of nutrition and lifestyle has long been recognized as a risk factor for poor health. However, while it is clear that nutrition and lifestyle have significant impact on health in general, different individuals exhibit very different responses to the same nutritional or lifestyle factor. This individual responsiveness is known to be influenced in large part by genetic makeup, also known as genotype.

A strengthening body of research is supporting the role of the interleukin-1, or IL-1, gene in relation to heart health. Individuals with a so-called IL-1 Positive Genotype have an exaggerated defense response that leads to elevated mediators such as IL-1 and CRP, and increased health risks.

With this in mind, the IL1 Heart Health clinical study was designed to evaluate the effect of the Nutrilite IL1 Heart Health dietary supplement on IL-1 and CRP. Our goal was not to reduce everyone's response; rather, it was to help balance the response in people genetically predisposed to elevated levels of IL-1 gene expression, production and CRP levels.

For this Independent Review Board-approved study, 64 healthy men and women who had been prescreened to determine their IL-1 genotype and CRP levels were recruited, gave their written informed consent to participate in the clinical trial, and had a medical exam by the physician Principal Investigator. All participants then gave blood samples before and after consuming the Nutrilite IL1 Heart Health Dietary Supplement, or a placebo, for 12 weeks. The blood samples were then analyzed for IL-1 gene expression, production, and CRP levels.

Compared to a person's value at the start of the study, Nutrilite IL1 Heart Health Dietary Supplement reduced IL-1 gene expression by a phenomenal 60% (top figure), IL-1 production by 40% (middle figure), and CRP by 20% or more in 45% of individuals (bottom figure). All of these reductions were significant compared to placebo tablets.

This controlled clinical study demonstrates that the Nutrilite IL1 Heart Health Dietary Supplement helps balance IL-1 gene expression for people who over express IL-1 as determined by the Gensona Heart Health Genetic Test. This exclusive formula also helps maintain normal CRP for those already in the normal range.

IL-1 Gene Expression

% of Baseline

*P<0.0001

IL1 Heart Health — Placebo

IL-1 Production

% of Baseline

*P<0.0001

IL1 Heart Health — Placebo

CRP

% of Subjects w CRP Lowering @ 12 Weeks

■ IL1 Heart Health
■ Placebo

**P=0.02
* P=0.03

>10%   >20%   >30%