

Clinical trial to explore link between vitamin D and cholesterol

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(PhysOrg.com) -- An unusual finding in previous studies of vitamin D-deficient patients has prompted Rockefeller University researchers to launch a new clinical study to determine whether there is a causative link between vitamin D supplementation and changes in cholesterol levels in people at risk for cardiovascular disease. Led by Manish Ponda, instructor in clinical investigation in Jan L. Breslow's Laboratory of Biochemical Genetics and Metabolism, the clinical trial is currently recruiting subjects.

Ponda's study was born from a peripheral finding of two other studies conducted in the Breslow lab in 2008-09. Data from one study examining the effects of vitamin D repletion on [insulin resistance](#) and another on the connection between vitamin D levels and endotoxemia in [kidney disease](#) suggested a possible link between the vitamin and levels of small LDL — the class of cholesterol molecules considered more insidious because they can more easily breach the walls of blood vessels and cause damage. So far, the data only points to an association; Ponda aims to determine whether there is a cause-and-effect relationship.

Accounting for seasonal variations, vitamin D deficiency affects roughly 20 to 25 percent of the population, and clinicians believe the lack may play a significant role in a number of common public health issues. "If you separate a large, random group of people into those who have high levels and low levels of vitamin D and just watch what happens to them over time, the first group lives longer and has fewer heart attacks," says Ponda, citing, among other publically available data, the National Health and Nutrition Examination Survey. "Right now, however, the level of evidence for vitamin D supplementation is epidemiologic. We need prospective data from controlled clinical trials to determine the benefits and risks of vitamin D supplementation. There may be an attendant risk for those who are already at higher risk of cardiovascular disease." If Ponda's hypothesis is

correct, his results would be highly relevant for doctors and patients managing cardiovascular care.

Because cholesterol is of greater concern for some patients than others, Ponda is limiting the scope of his study to people at elevated risk for cardiovascular disease. Eligible subjects will be split randomly into two groups: 75 people to take vitamin D supplements and 75 in a placebo control group. Subjects in the supplement group will be given 50,000 units per week of [vitamin D](#), an average supplement dose. Study investigators will take blood samples before and after eight weeks of supplementation/placebo and compare levels of small LDL cholesterol as well as other factors related to heart disease, such as glucose levels.

"Clinical trials are just as important for nutrients as for medications because no matter how good something may look on paper, or how intuitive it may seem, we can't assume there is an across-the-board benefit until we have the controlled evidence to prove it," says Ponda.

Provided by Rockefeller University

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