

## No benefit from high-dose multivitamins seen for HIV patients receiving antiretroviral therapy

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A new study by Harvard School of Public Health (HSPH) researchers suggests that, for HIV patients receiving highly active antiretroviral therapy (HAART) to treat HIV, there is no benefit from high- vs. standard-dose micronutrient supplementation—and that, in fact, high-dose supplements may cause harm. The study is the first large randomized trial to look at how high-dose multivitamin supplementation affects clinical outcomes among people on HAART.

The study appears in the October 17, 2012 issue of the <u>Journal of the American Medical Association</u> (*JAMA*).

Previous studies have shown that high doses of supplemental micronutrients help HIV patients that are not receiving HAART reduce disease progression and death, thus prolonging the time before HAART initiation is needed. The HSPH researchers wanted to know if high-dose multivitamin supplementation would provide a similar benefit for HIV patients on HAART; although HAART undoubtedly has major benefits, recovery of the immune system is incomplete, and the risks of mortality and opportunistic infections remain high especially in the first few months after HAART initiation.

The researchers, including lead author Sheila Isanaka, research fellow in the HSPH Department of Nutrition, and senior author Wafaie Fawzi, professor of nutrition, epidemiology, and global health and chair of the



Department of Global Health and Population at HSPH, studied a group of 3,418 patients with HIV who started HAART between November 2006 and November 2008 in seven clinics in Dar es Salaam, Tanzania. Half of the patients received high doses of supplements including vitamin B complex, vitamin C, and vitamin E; the other half received standard doses at the recommended dietary allowance level for a median duration of 15 months.

The results showed that high-dose supplementation had no effect on several key measures that reveal HIV disease progression—CD4 count, plasma <u>viral load</u>, <u>body mass index</u>, or <u>hemoglobin level</u> concentration—and did not reduce death or disease progression risks for HIV-infected patients. In addition, the researchers found that high doses of multivitamins increased patients' risk of having elevated levels of ALT, an enzyme associated with liver problems and other serious conditions.

"Although the provision of high-dose vitamin supplements has been found safe and efficacious among HIV-infected patients not receiving HAART, the results from this study show that the safety and efficacy of nutritional interventions in the context of potent combination therapies such as HAART need to be further examined," said Fawzi.

"This study provides no clear evidence of a benefit of high-dose micronutrient supplementation compared to standard-dose supplementation in adults receiving HAART, but it highlights the need for further research on how micronutrient supplements can be better positioned alongside antiretroviral drugs to reduce morbidity and mortality due to HIV," said Isanaka.

Micronutrients are key factors in maintaining immune function and neutralizing oxidative stress, and future studies could examine whether micronutrient supplements might be of benefit if they are offered with



food, or given in lower doses, or given only after HIV patients have acclimated to HAART therapy, she said.

**More information:** "Effect of High-Dose vs Standard-Dose Multivitamin Supplementation at the Initiation of HAART on HIV Disease Progression and Mortality in Tanzania: A Randomized Controlled Trial," Sheila Isanaka, Ferdinand Mugusi, Claudia Hawkins, Donna Spiegelman, James Okuma, Said Aboud, Chalamilla Guerino, and Wafaie Fawzi, *JAMA*, October 17, 2012, Vol. 208, No. 15

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