Effective treatments available for HIV patients not eligible for efavirenz regimens

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A new national clinical trial found HIV drug regimens that do not include efavirenz are effective as first-line antiretroviral therapy. The finding is important for patients who are not eligible for treatment with efavirenz, including women considering becoming pregnant and patients with a history of severe psychiatric disorders.

Drug combinations based on efavirenz are the first-line HIV therapy generally recommended by the U.S. Department of Health and Human Services and World Health Organization guidelines.

The study results are published in the *Annals of Internal Medicine*.

Researchers from the AIDS Clinical Trials Group (ACTG), sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) conducted the phase III, randomized study of three efavirenz-free regimens at 57 sites in the United States and Puerto Rico. The study included 1,809 participants age 18 or older with HIV-1 RNA levels greater than 1000 copies/mL and having had no previous treatment with antiretroviral therapy. Participants were followed for 96 weeks.

The study included three treatment groups: 300 mg/d of atazanavir with 100 mg/d of ritonavir; 800 mg/d of darunavir with 100 mg/d of ritonavir; or 400 mg/bid of raltegravir. All participants received 200 mg/d of emtricitabine and 300 mg/d of tenofovir disoproxil fumarate in addition to the assigned regimen.

The authors found that the three regimens attained high and equivalent rates of control of HIV in the blood and restored function of the immune system, but there were differences in tolerability. Tolerability of regimens containing raltegravir or ritonavir-boosted darunavir was superior to that of the ritonavir-boosted atazanavir regimen.

When tolerability and virologic response were considered together, raltegravir-based therapy was superior overall to both other therapies and ritonavir-boosted darunavir was superior to ritonavir-boosted atazanavir.

The study's overall principal investigator was Jeffrey Lennox, MD, professor of medicine at Emory University School of Medicine and Grady Memorial Hospital. Ighovwerha Ofotokun, MD, Emory associate professor of medicine, was principal investigator at the Grady study site in Atlanta.

"We are very pleased that our study showed the drug combinations tested, without efavirenz, are good options for initial HIV antiretroviral therapy. This is critical information for patients who cannot tolerate efavirenz, and we believe this head-to-head comparison will provide useful information to guide clinicians about choosing among them," says Lennox.

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