# HIV integrase inhibitor effective for patients beginning antiretroviral treatment

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A member of a new class of antiretroviral drugs is safe and effective for patients beginning treatment against HIV, according to researchers who have completed a two-year multisite phase III clinical trial comparing it with standard antiretroviral drugs.

The results are online and scheduled for publication in an upcoming issue of the Lancet.

Lead author of the Lancet article is Jeffrey Lennox, MD, professor of medicine (infectious diseases) at Emory University School of Medicine. Lennox is chief of Emory's HIV/AIDS clinical trials unit and vice-chair of medicine dealing with Grady Memorial Hospital.

"These results provide an additional potent, well tolerated treatment option for newly diagnosed patients with HIV infection," says Lennox.

Raltegravir, a HIV integrase inhibitor, is overall as effective as widely used efavirenz, a reverse transcriptase inhibitor, the researchers found. Raltegravir also had faster onset of action and fewer adverse side effects . In the clinical trial, both were combined with two other standard retroviral drugs, tenofovir and emtricitabine.

The trial included 566 patients from 67 medical centers on five continents. The "primary endpoint" of the trial was pushing viral levels below 50 copies per ml of blood by week 48. Of the raltegravir group, 86 percent reached that goal, compared with 82 percent of the efavirenz

group.

Half the raltegravir group reached the endpoint by week four, compared with less than 20 percent for the efavirenz group. In addition, the raltegravir group encountered fewer side effects such as headache, dizziness and elevation in levels of cholesterol.

Raltegravir inhibits the HIV integrase enzyme, which inserts the viral genome into the host cell's DNA. It was the first integrase inhibitor to be approved by the FDA. Other types of antiretroviral drugs inhibit HIV's protease or reverse transcriptase enzymes.

Guidelines from the U.S. Department of Health and Human Services currently recommend efavirenz or a protease inhibitor, in combination with tenofovir and emtricitabine, as a preferred drug regimen for adults beginning antiretroviral treatment.

Efavirenz, tenofovir and emtricitabine make up a once-a-day combination (Atripla) approved by the FDA in 2006. The authors note that raltegravir is usually taken twice a day, which may be more difficult for some patients. However, raltegravir's reduction in side effects and concerns about the ability of efavirenz to cause birth defects may be advantages for raltegravir, the authors say.

Raltetravir was approved by the FDA in 2007, but at first only for people infected with HIV that is resistant to other drugs. The results of this study contributed to the July 2009 decision by the FDA to expand the indication for raltegravir beyond only individuals infected with HIV that is resistant to other drugs.

Source: Emory University (news : web)