Norvir/Invirase Go Head-to-Head with Kaletra

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Early results from a 48-week clinical trial comparing Norvir(ritonavir)-boosted Invirase (saquinavir) to Kaletra (lopinavir plus ritonavir) suggest that both options are working similarly well in patients starting therapy for the first time, although the rate of virologic failure has thus far been higher in the Norvir/Invirase group. The 24-week data, presented at the fourth IAS Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2007), in Sydney, also indicate that patients taking Norvir-boosted Invirase are less likely to experienced elevated lipids than those taking Kaletra.

The GEMINI study is a 48-week Phase III clinical trial designed to compare standard twice-daily doses of Norvir-boosted Invirase and Kaletra, both combined with Truvada (tenofovir plus emtricitabine) in 337 HIV-positive people starting HIV treatment for the first time. The primary goal of the trial is to assess the number of patients with viral loads below 50 after 48 weeks of treatment.

The interim results were presented at IAS 2007 by Francois Raffi, MD, of the Hotel-Dieu University Hospital in Nantes, France.

After six months of treatment, 69 percent of patients in the Kaletra group had viral loads below 50, compared to 69.9 percent of patients taking Norvir-boosted Invirase. The difference between the two groups was not statistically significant, meaning it could have been due to chance.

CD4 count increases were also similar between the two groups, with gains of 127 cells seen in the Norvir/Invirase group and 134 cells in the Kaletra group—again, indicating no statistically significant difference.

Rates of virologic failure—defined as a viral load above 400 copies after 16 weeks in the study—did differ between the two groups. Among those taking Norvir-boosted Invirase, 10 (6.0 percent) were dubbed virologic failures, compared to only 3 (1.8 percent) patients in the Kaletra group.

Dr. Raffi explained that some failures were clearly due to nonadherence, but other cases could not be easily explained. In only two patients did resistance-associated mutations in HIV's protease gene arise—both in patients taking Norvir-boosted Invirase. The most common mutations, however, were those in the reverse transcriptase gene conferring resistance to the emtricitabine

in Truvada.

The authors also noted that 24 weeks of Norvir-boosted Invirase therapy was associated with a less serious increase in blood lipids (fats). Total cholesterol, for example, increased by 8.0 mg/dL in the Norvir/Sustiva group, compared to a 16.3 mg/dL increase in the Kaletra group. “Bad” LDL cholesterol increased by 3.7 mg/dL and 6.0 mg/dL respectively. As for triglycerides, a 0.6 mg/dL decrease was noted in the Norvir/Invirase group, compared to an 8.9 mg/dL increase in the Kaletra arm of the study. These differences between the two groups were statistically significant.

Dr. Raffi’s group said there were fewer cases of diarrhea among those treated with Norvir-boosted Invirase (6.7 percent) compared to those taking Kaletra (11.9 percent). It is worth noting, however, that most patients in the Kaletra group began therapy using the older gel-cap formulation of the drug, which is known to have a more pronounced effect on the gastrointestinal tract than the current tablet version of the medication.

Source:

Raffi F, Ward D, Ruxrungtham K, et al. **Saquinavir/r (SQV/r) BID vs. lopinavir/r (LPV/r) BID plus emtricitabine/tenofovir (FTC/TDF) QD as initial therapy in HIV-1 infected patients: the GEMINI study** [Abstract WEPEB027]. Program and abstracts of the fourth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention, Sydney, 2007.

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