Poor Viral Control With Once-Daily Viramune, Viread and Epivir

January 15, 2009

People on a once-a-day regimen of Viramune (nevirapine), Viread (tenofovir) and Epivir (lamivudine) had a very high risk of early virologic treatment failure, according to a study published in the February issue of the *Journal of Antimicrobial Chemotherapy*.

Researchers have been looking for ways to optimize the use of Viramune. Approved as a twice-daily medication, it is a leading treatment option for people new to antiretroviral (ARV) therapy. Its maker, Boehringer Ingelheim, is working on a longer-lasting formulation. In the meantime, scientists have conducted several studies of the existing formulation used once a day. Results, however, have not been consistent.

To explore the potential of once-daily Viramune in people starting ARV treatment for the first time, David Rey, MD from the Hôpitaux Universitaires, in Strasbourg, France, and his colleagues compared a once-daily Viramune regimen with a twice-daily Viramune regimen. The twice-daily regimen included Viramune and Epivir, but substituted Retrovir (zidovudine) for the Viread. Rey's team planned to enroll 250 patients in the study.

Rey and his colleagues quickly realized, however, that the once-a-day regimen was inferior. They conducted an unplanned interim analysis after just 71 patients had been recruited. The team found that 22.2 percent of those taking the once-daily regimen failed to respond to treatment right off the bat. In contrast, every patient on the twice-daily regimen had an initial response. Moreover, two people who had initially responded to the once-daily regimen later had a rebound of virus.

Confronted with this unanticipated result, the steering committee for the study stopped it early. The researchers state that the reason for the early failures on the once-daily regimen are not yet clear and require further research.