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Can oral ganciclovir prevent vision loss?

January 1, 1996 By Tim Horn

For many PWAs -- especially those with infections caused by cytomegalovirus (CMV) -- the Food and Drug Administration's (FDA) decision to approve an oral version of the anti-CMV drug Cytovene (ganciclovir) at the beginning of this year was a blessing.

CMV, a member of the herpesvirus family, can cause a variety of infections, including blindness and life-threatening disease. The only two treatments approved had been Cytovene or Foscavir (foscarnet), which requires daily IV infusions, usually for the rest of a patient's life. With FDA approval, it became possible to complete a short length of IV therapy and then switch to an oral dose of 12 capsules a day.

Even more exciting was the possibility that oral Cytovene could be used as a preventive drug (prophylaxis) against CMV infection; two clinical trials were conducted. The results of one were presented in October 1994 with much fanfare as a medical breakthrough in preventive medicine. But the results of the *second* trial delivered a sobering blow to physicians, researchers and activists.

So which study is correct? Before we pull the plug on CMV prophylaxis, it is important to understand the differences between the two trials. The first, sponsored by Cytovene manufacturer Syntex Laboratories, held that the oral drug was effective. In this study, 725 participants were given either oral Cytovene or placebo. Of the 486 participants on oral Cytovene, only 16 percent developed a form of CMV disease, whereas 30 percent on placebo did. What's more, only 11 percent of those on Cytovene compared to 20 percent of those on placebo developed sight problems from CMV retinitis.

With this good news, all eyes were fixed on another study being conducted by the Community Programs for Clinical Research on AIDS (CPCRA). This study was anything but reassuring. According to researcher Carol Brosgart, M.D., there was no statistical difference between those on oral Cytovene and those on placebo.

Without disparaging the findings of either research team, it is important to understand that the trials -- while similar in their randomized, placebo-controlled design -- differed significantly in their overall structure.

What difference does this make? “A world of difference,” says Kevin Frost of the American Foundation for AIDS Research. First of all, due to the findings of the Syntex study, the CPCRA was required to offer Cytovene to all participants half-way through their study. The switch-over seriously altered the so-called power of the trial in terms of yielding statistically significant results. “Also,” Frost says, “because CMV retinitis usually doesn’t set in until patients fall below 10 CD4 cells, the participants in the Syntex study were much easier to monitor.”

More important, participants in the Syntex study were monitored carefully by ophthalmologists, whereas those in the CPCRA study were monitored by primary physicians. The difference? Frost concludes, “Because symptoms of CMV retinitis may not manifest themselves until after CMV has caused extensive eye damage, the CPCRA study did not follow participants long enough to demonstrate the effectiveness of oral Cytovene based on symptoms.”

Where do we go from here? According to ophthalmologist Ronni M. Lieberman, M.D., a conclusion that can be drawn from *both* trials is the importance of ophthalmologic care for PWAs with fewer than 50 CD4 cells. “There is much to be gained from detecting CMV retinitis in its early stages, especially in the absence of symptoms.”

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