Quality of life outcomes of combination zalcitabine-zidovudine, saquinavir-zidovudine, and saquinavir-zalcitabine-zidovudine therapy for HIV-infected adults with CD4 cell counts between 50 and 350 per cubic millimeter. PISCES (SV14604) Study Group.

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Abstract

BACKGROUND: This double-blind study evaluated treatment with zalcitabine-zidovudine, saquinavir-zidovudine, or saquinavir-zalcitabine-zidovudine on the health-related quality of life of HIV-infected adults with CD4 cell counts between 50 and 350 cells/mm3.

METHODS: Nine hundred and ninety-three HIV-infected male or female quality of life substudy patients aged 18 years or older, with CD4 cell counts between 50 and 350 cells/mm3 naïve to antiretroviral therapy or with less than 16 weeks of zidovudine therapy, were randomly assigned to one of three daily regimens: zalcitabine 0.75 mg and zidovudine 200 mg every 8 h (ddC/ZDV); saquinavir 600 mg and zidovudine 200 mg every 8 h (SQV/ZDV); or saquinavir 600 mg, zalcitabine 0.75 mg and zidovudine 200 mg every 8 h (SQV/ddC/ZDV). The health-related quality of life was measured using the Medical Outcome Study HIV (MOS-HIV) Health Survey subscale and physical and mental health summary scores, and a global visual analogue scale (VAS) score. The primary health-related quality of life endpoints were the MOS-HIV physical and mental health summary scores.

RESULTS: After 24 weeks of treatment, no statistically significant differences were observed between the three treatment groups on physical health and mental health summary scores (global test P = 0.118). After 48 weeks of treatment, statistically significant differences among the groups were observed for physical health and mental health summary scores (global test P = 0.020); no change in physical health summary scores from the baseline were seen in the triple combination therapy, whereas the ddC/ZDV combination therapy group showed decreases from baseline in physical health summary scores (P = 0.008). Six of the 10 individual MOS-HIV subscale scores and the VAS scores showed results consistent with the physical health summary endpoints after 48 weeks of therapy. No statistically significant differences in baseline to 48 week changes in MOS-HIV subscale or summary scores were seen between the ddC/ZDV and SQV/ZDV groups (P > 0.05).