Functional status and well-being in a placebo-controlled trial of zidovudine in early symptomatic HIV infection.


Department of Health Policy and Management, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, MD 21205.

Abstract

To determine the effect of zidovudine on functional status and well-being in patients with early symptomatic human immunodeficiency virus (HIV) infection, 70 subjects in a randomized, placebo-controlled trial (ACTG Protocol 016) were observed for 1 year using a brief quality-of-life questionnaire. Thirty-four subjects were assigned to placebo and 36 subjects to zidovudine, 200 mg orally every 4 h (1,200 mg daily). Functional status and well-being were measured every 3 months using a 30-item self-administered questionnaire derived from health ratings from the Medical Outcomes Study. The mean changes from baseline for zidovudine versus placebo groups were compared using paired and two-sample t tests. Subjects receiving a placebo reported better quality of life compared to baseline than subjects receiving zidovudine at 24 weeks for all dimensions of well-being, including overall health, energy, mental health, health distress, pain, and quality of life. The difference between the two groups' changes from baseline for overall health was 11.5 points on a 100-point scale (p = 0.02), and 11.1 points for energy (0.002). There were no differences between changes from baseline along various dimensions of functional status (physical, social, role, and cognitive function). At 52 weeks both groups reported worse overall health than at baseline, and changes in scores were more similar for the two groups. Although zidovudine has previously been demonstrated to delay progression of disease for patients with mildly symptomatic HIV infection, early in treatment the net effect of a 1,200 mg daily dose of zidovudine may diminish patients' subjective well-being. (ABSTRACT TRUNCATED AT 250 WORDS)