IMPACT OF ENFUVIRTIDE ON HEALTH-RELATED QUALITY OF LIFE.

Cohen CJ, Clumeck N, Molina JM, Thompson M, Patel K, Wintfeld N, Green J; IAS Conference on HIV Pathogenesis and Treatment (2nd : 2003 : Paris, France).

Antivir Ther. 2003; 8 (Suppl.1): abstract no. 1148.

Community Research Initiative of New England, Boston, USA

OBJECTIVES: HIV disease and therapy can affect health-related quality of life (HRQoL). This study was designed to investigate the impact of treatment with enfuvirtide, the first in the new class of HIV fusion inhibitors, on HRQoL. METHODS: 1013 treatment-experienced HIV-1-infected individuals enrolled in two Phase III trials (TORO 1 and TORO 2) were randomized to receive either enfuvirtide self-administered by subcutaneous injection plus an optimized background (OB) regimen or OB alone. Of these, 995 individuals received treatment and had at least one follow-up visit. Participants were asked to complete a Medical Outcomes Study (MOS)-HIV questionnaire, a comprehensive measure of HRQoL, at baseline (BL) and at 4, 8, 16 and 24 weeks. Analysis of co-variance (ANCOVA) was used to evaluate changes in the 10 MOS-HIV scale scores and two MOS-HIV summary scores (physical health and mental health). Least squares means were used to test for between-group differences. RESULTS: At BL there were no significant between-group differences in any HRQoL measure. Almost all MOS-HIV scores improved over time and showed a greater trend toward improvement in the enfuvirtide + OB arm compared with OB alone. There were no statistically significant improvements from BL favouring the OB arm. At 24 weeks the enfuvirtide arm showed a statistically significant improvement in score on four scales [general health, energy/fatigue (vitality), health distress and quality of life] and one summary score (mental health) compared with the OB alone arm. There were no other statistically significant between-group differences for the MOS-HIV summary scores at any time point. Improvements in the general health scale were statistically significantly higher for patients in the enfuvirtide + OB arm compared with the OB alone arm at all post-baseline time-points. CONCLUSIONS: The addition of enfuvirtide to an OB regimen does not adversely affect and may improve HRQoL when self-administered for 24 weeks by treatment-experienced, HIV-1-infected individuals. The trial is ongoing and a further analysis using 48 week data is planned.

Publication Types:
- Meeting Abstracts

Keywords:
- Acquired Immunodeficiency Syndrome
- HIV Envelope Protein gp41
- HIV Fusion Inhibitors
- HIV Infections
- HIV Seropositivity
- HIV-1
- Health
- Humans
- Life
- Peptide Fragments
- Quality of Life
- Questionnaires
- enfuvirtide
- immunology

Other ID:
- GWAIDS0023801

UI: 102263425