Retrovirology

Poster presentation

Randomized, Double-blind, Placebo Controlled Phase III Trial of Oxymetholone for the Treatment of HIV Wasting and Lipodystrophy

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Purpose of the Study

Although HAART has greatly impacted treatment of HIV infection, lipodystrophy and HIV wasting still represent unsolved problems in HIV therapy and patient care. Oxymetholone, a testosterone derivative, has been shown to promote weight gain in AIDS-associated wasting.

Methods

We analyzed the effects of oxymetholone [50 mg BII) and TII)] in a randomized (1:1:1), double-blind, placebo-controlled phase III study with 92 subjects (all on ART) experiencing unintended weight loss>10% of ideal weight according to *Broca* with special emphasis on body composition measurement 80 patients (69 men,11 women, mean age:38,8 years) completed the 16-week double-blind study phase.

Results

Mean weight gain was +3.7 ± 3.5 kg and +3.1 ± 2.7 kg in the oxymetholone groups [BII); n = 25 vs TII); n = 27] as opposed to +0.97 ± 3.4 kg in the placebo were observed in body cell mass (30.6 before vs 32.5 after therapy), lean body mass [56.3 before vs 59.0 after therapy in the BII) group] and body mass index (21.4 before vs 22.1 after therapy) exclusively in oxymetholone-treated patients. The extracellular mass to body cell mass ratio,($p < 0,0001$). Total body fat was unchanged by oxymetholone treatment. Adverse events were mainly hepatic occurring in 14% of oxymetholone-treated patients with significant elevations of AST, ALT and GGT;2 patients (7.4%) in the BII) arm experienced grade 3 and 4 liver toxicity compared with 6 [21.4%) in the TII] arm.

Conclusion

Oxymetholone was found to have true anabolic effects in a double-blind, placebo-controlled phase III trial. The (BII) (100 mg/d) regimen appeared equally effective to TII) (150 mg/d) dosing while displaying reduce liver toxicity. Due to its favourable protein anabolism, it may be recommended for therapy of wasting and lipodystrophy I HIV-infected subjects.