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SHORT-TERM METABOLIC AND ANTHROPOMETRIC EFFECTS OF A PLACEBO-CONTROLLED TRIAL OF PREDNISONE IN HIV-1-INFECTED INDIVIDUALS

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Glucocorticoid use in non-HIV-infected populations usually results in an increase in HDL cholesterol, development of insulin resistance and an increase in total and truncal fat. Little is known about its effect when given to HIV-1-infected individuals. ACTG 349 was a phase II, randomized, multi-centre, double-blinded, placebo-controlled study of the immunological and virological effects of prednisone on HIV infection. During the initial 8 weeks of the study period, the effects of prednisone on lipid profile, glucose homeostasis and body composition parameters were evaluated by analysis of fasting blood specimens and measurement of various body circumferences performed at baseline and at approximately week 8 of study. HIV-1-infected individuals on stable antiretroviral (ARV) therapy consisting of at least two FDA-approved anti-HIV agents were randomized to receive either prednisone 40 mg/day or prednisone placebo in addition to their ARV therapy during this initial 8 week period of study. Emergence of data indicating a possible risk of avascular necrosis with glucocorticoid use led to early closure of the study. We report the metabolic and body composition analysis completed in 23 subjects who had both baseline and approximately week 8 data gathered prior to study closure. In an as-treated analysis of the week 8 responses, the prednisone arm showed increases in HDL and total cholesterol compared to the placebo arm (median change from baseline prednisone versus placebo: HDL 23.5 mg/dl versus 1 mg/dl, $P<0.001$; T cholesterol 39 mg/dl versus 3 mg/dl, $P=0.016$). A significant positive correlation was found between changes in CD4 and change in HDL cholesterol (rank correlation=0.62, $P=0.031$). No significant treatment arm differences were detected in

LDL cholesterol, triglycerides, insulin, pro-insulin, c-peptide, glucose or in insulin sensitivity by HOMA. An increase in waist circumference measured at the level of the umbilicus was seen in the prednisone arm compared to the placebo arm without differences in body mass index. No differences were detected in neck, mid-arm, mid-thigh, hip, other waist circumferences, or in waist/hip ratios. In general, we conclude that the metabolic and anthropometric effects of prednisone in the HIV-1-infected individuals are similar to those reported in the non-HIV-1-infected population.

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