

# 3rd International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV



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## Abdominal CT-scan sub-study of study DPC006

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**BACKGROUND:** Fat redistribution (subcutaneous loss and/or visceral accumulation) has been associated with antiretroviral therapy.

**OBJECTIVE:** To assess the impact of three highly active antiretroviral therapy regimens on fat distribution over a 2-3-year period.

**METHODS:** Non-randomized, cross-sectional, posthoc sub-study of DPC 006 comparing efavirenz plus zidovudine plus lamivudine, with indinavir plus zidovudine plus lamivudine, to efavirenz plus indinavir in therapy-naive subjects. Willing subjects underwent an abdominal CT-scan (including a section at the level of the umbilicus or fourth lumbar vertebra) at their next scheduled study visit with a 1-year follow-up scan. An independent, central reader read all scans in a blinded fashion. Comparisons were made using the Wilcoxon test.

**RESULTS:** Three-hundred-and-seventy-three subjects enrolled in this sub-study. There were no statistical differences between arms in demographics or baseline characteristics. The median time from study start to first scan was 738 days and to the follow-up scan, 1106 days. Two-hundred-and-seventy-seven subjects had both first and second scans. The median subcutaneous fat at first scan ranged from 254.8 to 331.1 cm<sup>2</sup> (not significant). The median change between scans was -87.6, -128.5 and -117.5 cm<sup>2</sup> for the efavirenz plus zidovudine plus lamivudine, indinavir plus zidovudine plus lamivudine and efavirenz plus indinavir arms, respectively (significant changes between scans within

all arms,  $P < 0.05$  efavirenz plus zidovudine plus lamivudine versus indinavir plus zidovudine plus lamivudine). The median visceral fat at the first scan ranged from 123.6 to 150.4 cm<sup>2</sup> (not significant). The median change in visceral fat was -6.7, -13.7 and -7.6 cm<sup>2</sup> for the efavirenz plus zidovudine plus lamivudine, indinavir plus zidovudine plus lamivudine, and efavirenz plus indinavir arms, respectively (not significant within or between arms). The 75th percentile for change in visceral fat accumulation was threefold higher for the indinavir plus zidovudine plus lamivudine arm than the efavirenz plus zidovudine plus lamivudine or efavirenz plus indinavir arms (94.6, 32.2 and 32.8 cm<sup>2</sup>, respectively).

**CONCLUSIONS:** In this *post hoc* assessment of fat redistribution measured by abdominal CT-scan significantly more subcutaneous fat loss was noted in subjects receiving indinavir plus zidovudine plus lamivudine than efavirenz plus zidovudine plus lamivudine; however, significant subcutaneous fat loss between scans was noted for all arms. Though no difference in median change in visceral fat was noted between or within arms, the 75th percentile for visceral lipo-accumulation was threefold higher for the indinavir plus zidovudine plus lamivudine arm compared with the two other arms.

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