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CHANGES IN LIPID AND LABORATORY PARAMETERS DURING TREATMENT WITH SAQUINAVIR/RITONAVIR 1000/100 MG TWICE DAILY WITH NO NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS IN HEALTHY VOLUNTEERS

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M Kurowski¹, AM Hill² and C Moecklinghoff³

¹HIV-LAB, Berlin, Germany; ²Roche, Welwyn, UK; ³Roche, Welwyn, UK

BACKGROUND: Hyperlipidaemia has been linked with increased risk of lipodystrophy, pancreatitis and coronary heart disease. Ritonavir has shown dose related rises in triglycerides in dose ranging trials; other boosted protease inhibitors (PIs) and nucleoside reverse transcriptase inhibitors (NRTIs) may raise lipid levels.

METHODS: In a single centre open-label 2x2 crossover pharmacology study, 24 male healthy volunteers patients were randomized to receive saquinavir/ritonavir at a dosage of 1000/100 mg twice daily, with two saquinavir formulations (Fortovase and Invirase) for 10 days each. Fasting levels of triglycerides, cholesterol and other laboratory parameters were measured at day 1, day 10 and day 20 of the trial. Detailed data on adverse events were recorded during the two phases of the trial.

RESULTS: Complete lipid data were available for all volunteers throughout the trial. None of the volunteers experienced a Grade 3 or 4 lipid toxicity during the trial. Median levels of triglycerides and cholesterol were unchanged during the trial - median triglyceride levels were 165 mg/dl at baseline and 169 mg/dl at day 20; median cholesterol levels were 198 mg/dl at baseline and 192 mg/dl at day 20. Median creatinine levels were 0.95 mg/dl at baseline and 0.90 mg/dl at day 20. Levels of bilirubin and liver enzymes (AST, ALT, GGT) were similarly unchanged. Adverse events were predominantly gastrointestinal and occurred initially and most frequently during the Fortovase phases of the cross-over trial.

CONCLUSIONS: Saquinavir can be boosted with low dose ritonavir (100 mg twice daily) without short-term abnormalities in lipid or other laboratory parameters. By contrast, elevated lipid levels and liver enzyme abnormalities have been observed in short-term Phase I healthy volunteer trials with higher doses of ritonavir (either with or without saquinavir). Lipid elevations have been observed with ritonavir boosted amprenavir, while atazanavir treatment has led to elevated bilirubin levels.

Presenting author: M Kurowski

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44

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