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A RANDOMISED IMMEDIATE VERSUS DELAYED REPLACEMENT STUDY OF TRIZIVIR AS A SUBSTITUTE FOR TWO NRTIS PLUS EFAVIRENZ IN PERSONS EXPERIENCING CNS SYMPTOMS

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Graeme Moyle, Desmond Maitland, Jessica Osorio, Sundhiya Mandalia and Brian Gazzard

Chelsea and Westminster Hospital, London, UK

BACKGROUND: Efavirenz (EFV) is associated with CNS disturbances, such as sleep disturbances and mood changes, which may persist in some patients.

METHODS: Individuals with HIV RNA <50 copies/ml on initial therapy with two NRTIs plus EFV and reporting persistent CNS disturbances replaced the NRTIs with Trizivir and were randomised to either continue efavirenz or matching placebo for 4 weeks. After week 4 all patients remained on Trizivir alone. Evaluations through week 24 included hospital anxiety and depression (HADS) score, 10 sleep dimensions by VA scale, biochemical and lipid parameters and HIV disease markers.

RESULTS: 18 individuals were screened and 16 randomised. No abacavir hypersensitivity (HSR) or HIV-1 RNA rebounds were observed. One individual modified zidovudine to atazanavir. Switching therapy was associated with significant improvements in HADS scores from baseline to week 24 ($P=0.01$ both groups combined) with both anxiety ($P=0.008$) and depression ($P=0.022$) scores improving. Differences were not observed between groups at any time point. Combined sleep VA assessments did not significantly change although scores for sleep restfulness, dream vividness and morning sluggishness all improved. Total cholesterol (0.7 mmol/l), LDL (0.5 mmol/l) and HDL (0.16 mmol/l) decreased significantly through week 24.

CONCLUSION: Switching from 2NRTI + EFV to Trizivir is effective and well tolerated in initial therapy patients. HADS scores and some sleep characteristics improve

gradually with switching. Total, LDL and HDL cholesterol levels decline following switching.

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