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Abstract (poster session)

Treatment of HIV infection in subjects with tuberculosis: prospective, randomised, multicentre study comparing a PI-containing regimen (lopinavir / TDF /3TC) with an NNRTI-containing regimen (efavirenz / TDF / 3TC)

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Trial Design: Prospective, multicenter, open-label, randomised. Methods: PARTICIPANTS:Consecutive patients with HIV infection and diagnosis of active tuberculosis observed at 18 Italian study sites. Eligible HIV patients had peripheral CD4+ T cell counts <= 300/ mm3. Intervention: Eligible subjects were randomly assigned to one of the following regimens: arm A standard 4-drug TB regimen for 2 months followed by a 2-drug continuation phase in association with efavirenz 800 mg/QD and a standard backbone of emtricitabine 200 mg + tenofovir 300 mg QD. Arm B: TB regimen with rifabutine as substitute for rifampicin 150 mg every other day in association with lopinavir/ritonavir 400/100 mg BID and the standard backbone. Objective: To compare the completion rate of combined TB and HIV treatment regimens. Outcome: The primary outcome was the rate of completion of dual TB and HIV treatment, measured at the end of standard TB therapy. Randomisation: Patients were assigned to one of the study arm according to a central randomisation list at TB treatment initiation. Eligibility criteria were evaluated before randomisation and re-checked at the time of final diagnosis. Results: Patients were enrolled between July 2005 and December 2010. Recruitment was closed before reaching the target sample of 200 patients:121 patients were randomised, 61 to arm A and 60 to arm B. Ninety-six patients (79.3%) were eligible for the study, 49 in arm A and 47 in arm B. Most of eligible patients were male (74%), Italian (71%), had acquired HIV infection heterosexually route (50%), had a mean age of 42 years (SD + 11 years) and a mean baseline CD4+ T cell count of 147 (SD + 144). Demographic clinical and viro-immunological characteristics at baseline were similar in the two groups. The completion rate was 57.1% (28/49) in arm A compared to 48.8% (22/47) in arm B (p= 0.41). The initial treatment was not completed due to major adverse events in 10.2 % (5/49) of patients in arm A vs. 17.0% (8/47) in arm B (p= 0.38). Eighteen percent of patients (9/49) in arm A vs. 25.2% (25/47) in arm B were lost to follow up. Two persons died in each arm. Conclusions: The treatment completion rate was similar in the two arms. There is a trend towards a higher rate of major adverse events and default among patients in the arm B. Trial registration: EUDRACT number 2005-245097-05 Funding: The study was partially funded by the V and VI Italian AIDS Research Programme