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ID *489*

DRV/R FDC plus 3TC for HIV-1 treatment naive patients: Week 48 results of the ANDES study

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- **Background:** Dual therapy has been explored in different studies. A generic fixed dose combination (FDC) of DRV800/ritonavir100 mg is available in Argentina. We designed a study to compare efficacy and safety of this FDC plus 3TC to standard-of care HAART based on the same drugs plus tenofovir. ClinicalTrials.gov Identifier: NCT02770508
- **Methods:**ANDES is a randomized, open-label, phase IV study, designed to compare dual therapy (DT) with DRV/RTV (800/100 mg) FDC, plus 3TC (300 mg), to triple therapy (TT) with DRV/RTV (800/100 mg) plus 3TC/TDF (300/300mg),FDC in treatment-naïve HIV-1 infected patients. Primary endpoint: proportion of patients with viral load (pVL) <50 copies/mL at week 48 (FDA snapshot -ITTe analysis) Preplanned week 24 analysis was presented at IAS 2017.Week 48 results are reported here.
- **Results:** Out of 182 patients screened, 145 were randomized to receive: DT (n75) or TT (n70). At baseline 92% were on CDC stage A: 24% had pVL> 100,000 copies/mL(table 1)**.** At week 48, 93 % of patients on DT and 94% on TT achieved pVL <50 copies/mL, difference (95% CI): -1.0% (-7.5; 5.6%). 92% of patients with baseline pVL>100,000 copies/mL showed 92% response in TT arm and 91% in DT. (figure 1 and table 2) One patient presented virological failure at W48 (TT arm).Per-protocol analysis: 99% were responders in TT arm and 100% in DT arm. Median CD4+ change between BSL and week 48 was similar in both arms (TT: 200 cells/mm3; DT:246 cells/mm3; (p:0.20)(figure 2) Thirty six grade 2-4; possible/probable related adverse events (AEs)were reported among 28 patients(TT:17;DT:11), the most frequent AEs were gastrointestinal (TT: 14%; DT: 7%; p:0.17) and rash (TT:7%; DT: 8%;p:0.95). Laboratory abnormalities were similar in both arms except regarding total cholesterol (change from BSL to W48: TT: 4%; DT: 19%; p: 0.01).LDL-cholesterol and triglycerides showed a non-significant trend in favor of TT(TT: 6%/DT 14% and TT: 14%/DT: 25% respectively. AEs leading to discontinuation were rare and similar between arms. No treatment-related SAEs or deaths were reported
- **Conclusion:** A generic FDC of DRV/RTV plus 3TC showed non-inferiority to a standard of care triple drug regimen with ritonavir-bosted Darunavir in FDC plus TDF/3TC at 48 weeks.This study adds further evidence about the efficacy of drug-sparing regimens in treatment-naïve patients

Table 1. Demographics at screening

	Global (n=145)	Triple therapy (n=70)	Double therapy (n=75)
Age	33.1±9.9 30 (25.5-39.5)	32.5±8.4 30 (26-38)	33.7±11.1 30 (24-42)
Males	131 (91%)	61 (88%)	70 (93%)
Hispanic/Latino	102 (71%)	49 (71%)	53 (71%)
MSM/Bisexual	101 (73%)	48 (71%)	53 (76%)
CDC Stage B	11 (8%)	5 (7%)	6 (8%)
Viral Load (log)	4.5 (4.0-5.0)	4.5 (3.9-5.0)	4.6 (4.1-5.1)
CD4 count	383 (286-562)	366.5 (275-544)	419 (290-564)
CD4 %	19 (14-25)	19 (14-25)	19 (14-25)
VL >100000 c/mL (Baseline)	35 (24%)	15 (22%)	20 (27%)
* All patients were on CDC stage A or B			

Figure 2 :CD4 count increase (means ± standard error of the mean)

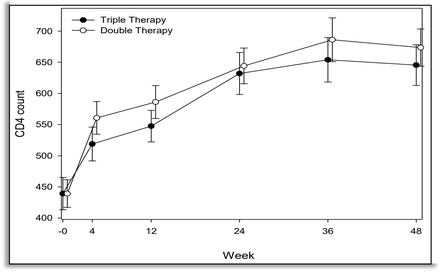

Figure 1. Proportion of patients with plasma HIV-1 RNA less than 50 copies/mL

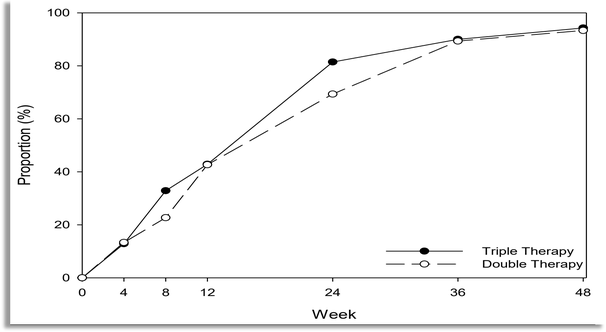

Table 2. Efficacy analysis

	Global	Triple therapy	Double therapy	Difference (95% CI)
Primary outcome: VL<50 c/mL at week 48				
ITT snapshot, (n=145)	136 (94%)	66 (94%)	70 (93%)	-1.0% (-7.5 ; 5.6%)
ITT snapshot, baseline VL > 100.000 c/ml (n=35)	32 (91%)	12 (92%)	20 (91%)	-1.4% (-17.2 ; 14.4%)
Observed (n=140)	136 (99%)	66 (99%)	70 (100%)	1.5% (-0.9% ; 3.9%)

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ESTUDIO ANDES
DRV/RTV/3TC COMBINADOS PARA EXPLORAR TOLERABILIDAD, EFICACIA Y SEGURIDAD