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A Prospective Randomized trial on Abacavir/lamivudine plus DArunavir/r or Raltegravir in patients with CD4<200 cells/uL (PRADAR Study)

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Background

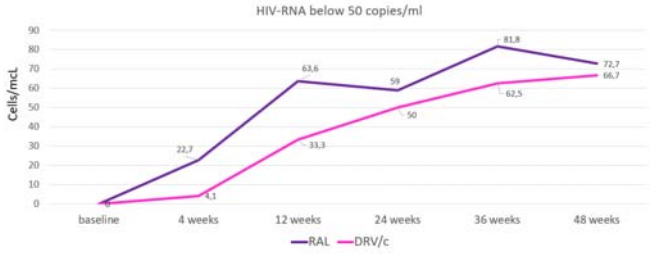
HIV late presentation is still a major problem worldwide and patients represent a clinical challenge. Very few data are available on treatment in this population.

Material and methods

A prospective, multicenter, randomized open-label, 2 arm, phase-3 trial comparing the 48-week virological response of two different regimens: abacavir/lamivudine + darunavir/ritonavir (DRV/r) vs abacavir/lamivudine + raltegravir (RAL)) is conducted in a population of antiretroviral naive, HIV+ individuals HLAB5701 negative, presenting for care with CD4+ counts < 200/mm3 and a viral load (VL)<500000 copies/mL. Primary endpoint was to calculate the proportion of patients with undetectable viremia (VL<50 copies/mL) after 48 weeks, secondary endpoints were to observe changes in CD4+ cell count from baseline through week 48 and time to virological rebound.

Variable	RAL	DRV/c
Gender (male/female; number)	19/3	19/5
Age (years; median & IQR)	41 (13)	35 (16)
Risk factor for HIV (number)		
MSM	9	12
Heterosexual contacts	11	10
IVDU	1	1
Other	1	0
unknown	0	1
CDC stage (number)		
A	10	15
B	5	3
C	7	6
HIV RNA (copies/ml; median & IQR)	89731 (99356)	112250 (204238)
CD4 (cells/mcL; median & IQR)	108 (145)	117 (141)
CD8 (cells/mcL; median & IQR)	701 (672)	817 (461)

ITT analysis (proportion)



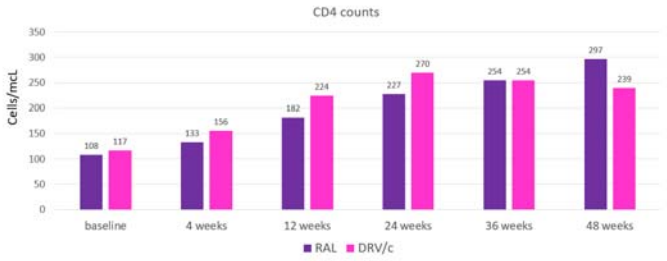
Results

In 3 years 53 patients were screened and 46 enrolled: 22 randomized to RAL (19 males, median CD4+ 108 cells/uL, median VL 89731 copies/mL) and 24 to DRV (CD4+ 117, VL 112250). 7 patients were excluded, 4 because of a VL >500000 copies/mL and 3 for HLAB5701 positivity. The snapshot analysis at 48 weeks showed a virologic success of 77.3 % in RAL and 66.7% in DRV. Time to starting treatment was 34.5 days in RAL and 53 days in DRV. At the as treated analyses the median increase in CD4+ was 297 in RAL and 239 in DRV. No difference in total cholesterol was found, while triglycerides were higher in DRV arm. No statistical analyses were performed due to the low number of patients enrolled.

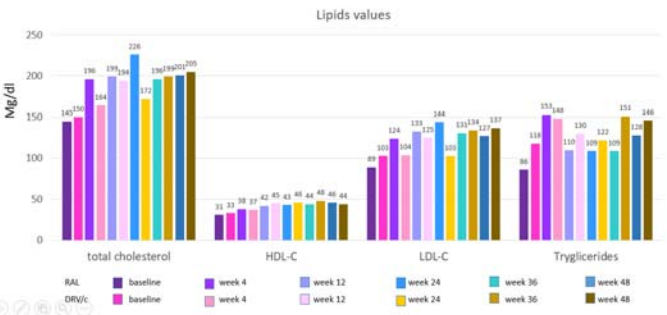
Conclusion

Patients Late presenters are frequent but very difficult to enroll in clinical trials. In these patients, the test and treat strategy is rarely applicable. The rate of virologic success is similar to that described in the literature and very far from results of the recent trials in naïve patients.

As treated analysis (median values)



As treated analysis (median values)



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