Screening Characteristics of Participants in an Open label, Multi-Centre, Randomised Controlled Trial Investigating Integrase Inhibitor Versus Boosted Protease Inhibitor Antiretroviral Therapy for Late Presenters with Advanced HIV Disease (LAPTOP)

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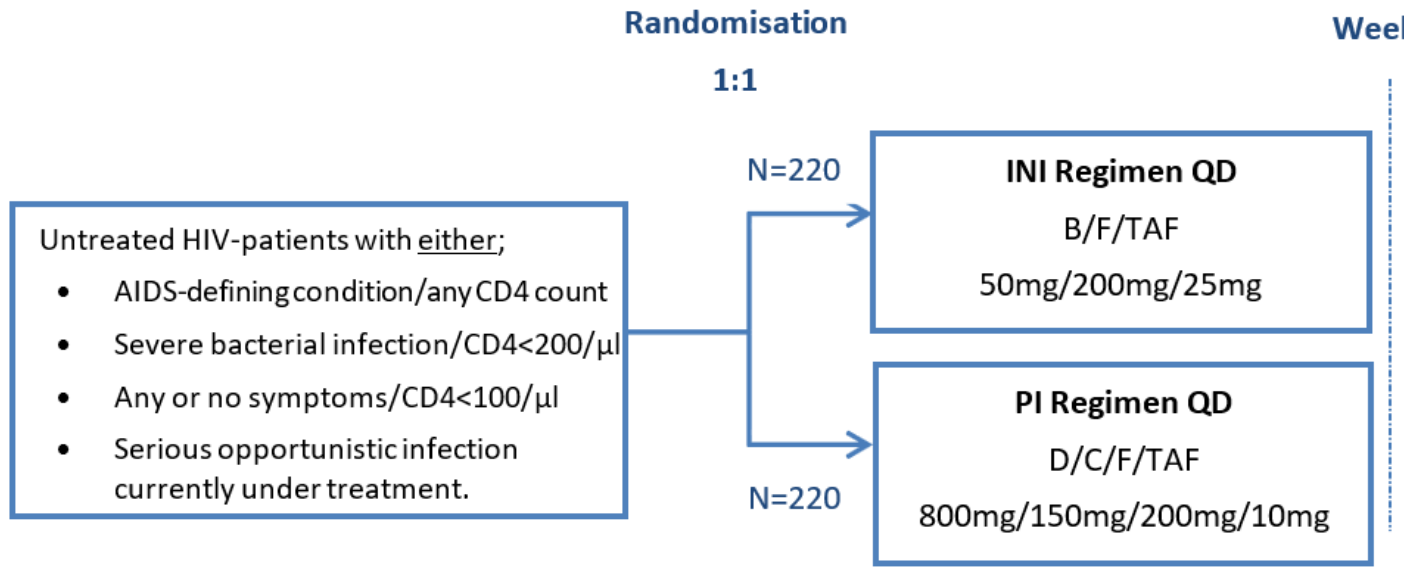
Background

- Most first line HIV treatment randomised controlled trials recruit individuals who have low baseline viral loads, high CD4 counts, fewer co-morbidities, drug-drug interactions, and other treatment failure risks than those presenting with advanced disease.
- We conducted the LAPTOP trial in people with advanced disease across 7 European countries; here we present participants' clinical characteristics at Screening.



Methods

This is a 48-week, open-label, European, multi-centre, non-inferiority, controlled trial comparing outcomes for people with advanced HIV disease randomised 1:1 to receive bictegravir (BIC) or darunavir (DRV)/ cobicistat co-formulated with emtricitabine (FTC)/ tenofovir alafenamide (TAF). Inclusion criteria include untreated HIV-1, HIV-RNA >1,000 copies/ml, and at least one of the following:

1) AIDS-defining condition/any CD4 count;
2) Severe bacterial infection/CD4<200/µl;
3) Any or no symptoms/CD4<100/µl;
4) Serious opportunistic infection currently under treatment.

HIV-RNA and Immune Status at Screening	Total (N=447)
HIV RNA viral load, log10 copies/mL, median (IQR)	5.6 (5.1-6.0)
<100,000	83 (18.6)
100,000 – 500,000	169 (37.8)
>500,000	195 (43.6)
CD4+ count (cells/µL)	41 (17-79)
<50	258 (57.7)
50 – 99	126 (28.2)
100-199	51 (11.4)
≥200	12 (2.7)
CD4+ (%)	5.0 (2.3-8.3)
CD8+ count (cells/µL), median (IQR)	N=443 475 (299-753)
CD8+ (%)	N=436 65.1 (54.0-73.9)
CD4/CD8 ratio, median (IQR)	N=443 0.08 (0.04-0.14)
<0.10	257 (58.0)
0.10 – 0.30	157 (35.4)
>0.30	29 (6.5)

Results

447 screened individuals (80.8% male, 66% white or white mixed ethnicity, median age: 43 years, IQR 35-53 years) were analysed.

Body Weight Median (IQR) at Screening	
Body mass index (BMI, kg/m2)	N=443 22.3 (19.9-24.5)
Weight, Kg	N=445 67 (58-75)

Demographics at Screening	Total (N=447)
Age (years), median (IQR)	43 (35-53)
Gender	
Male	361 (80.8)
Female	86 (19.2)
Child-bearing potential	52/86 (60.5)
Ethnicity	
White caucasian	278 (62.2)
African	50 (11.2)
Black	36 (8.1)
Other	36 (8.1)
Asian	21 (4.7)
White mixed	17 (3.8)
Caribbean	9 (2.0)
Inclusion reasons	
AIDS with any CD4 cell count	220 (49.2)
Severe bacterial infection and CD4 cell count < 200	22 (4.9)
Asymptomatic with CD4 cell count < 100 and viral load > 1000	171 (38.3)
Currently receiving treatment for an opportunistic infection	34 (7.6)
Days from HIV diagnosis to screening, median (IQR)	14 (7-24)
Medical history	
No	16 (3.6)
Yes	430 (96.4)
Missing	1

Resistance Data at Screening	
Resistance test available, n (%)	425 (95.1)
Among those with resistance tests, number of days between resistance test and screening visit [Median (IQR)]	4 (0 - 9)
No High-level or intermediate resistance to any ARV	398/425 (93.6)
NRTI resistance, n (%) High-level; intermediate resistance	3 (0.7); 2 (0.5)
NNRTI resistance, n (%) High-level; intermediate resistance	16 (3.8); 3 (0.7)
PI resistance, n (%) High-level; intermediate resistance	0 (0); 1 (0.2)
INSTI resistance, n (%) High-level; intermediate resistance	3 (0.7); 1 (0.2)
Resistance to more than one class	2 (0.5)
Please note resistance interpretation was made using the Stanford algorithm (last updated on 2023-11-05).	

Conclusions

Almost half of LAPTOP trial participants were diagnosed after an AIDS-defining condition was present, and over half had CD4 counts less than 50 cells/µl. The trial will generate important safety and efficacy data for current ART in this population.

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