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A Randomized Trial Switching Adults ≥ 60 Years Old From First-Line ART to B/F/TAF: Week 48 Results

Loice Achieng Ombajo[1], Jeremy Penner[1,2], Joseph Nkuranga[1], Edwin Otieno[1], Jared Mecha[1], Simon Wahome[3], Florentius Ndinya[4], Victor Omodi[1], Ruth Wanjohi[5], Sanjay Bhagani[6], Anton Pozniak[7]

[1]University of Nairobi, Nairobi, Kenya, [2]University of British Columbia, Vancouver, Canada, [3]Kenyatta National Hospital, Nairobi, Kenya, [4]Jaramogi Oginga Odinga Teaching and Referral Hospital, Kisumu, Kenya, [5]The Nairobi Hospital, [6]Royal Free London Foundation Trust, London, United Kingdom, [7]London School of Hygiene and Tropical Medicine, London, United Kingdom

BACKGROUND

- Age-related co-morbidities and overlapping toxicities of some antiretrovirals (ART) limit treatment options for the aging people living with HIV
- We evaluated the efficacy and safety of switching older adults (60 years old and above) from their first-line regimen to bictegravir / emtricitabine / tenofovir alafenamide (B/F/TAF)

METHODS

- The B/F/TAF-elderly study is a 96-week open-label, randomized, active-controlled, non-inferiority trial conducted at two sites in Kenya
- Participants are HIV-1 positive older adults (≥60 years) on any first line regimen with HIV RNA <50 copies/mL for at least 12 weeks prior to enrolment and randomized 1:1 to switch to B/F/TAF or continue current ART regimen (CAR) (Figure 1)
- The co-primary endpoints are
  - proportion of participants with HIV-1 RNA ≥50 copies/mL at week 48 in the intention-to-treat-exposed population using FDA Snapshot algorithm with a non-inferiority margin of 4%
  - mean percentage change in lumbar spine bone mineral density (BMD) from baseline to week 48

RESULTS

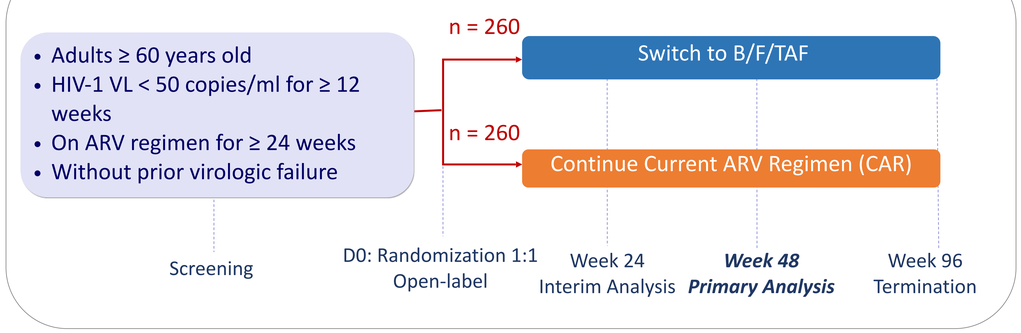
- Between Feb and May 2022, 520 participants were randomized (260 B/F/TAF, 260 CAR); 296 of these were enrolled for BMD monitoring (143 B/F/TAF, 153 CAR)
- Baseline characteristics were balanced between arms (Table 1)

Table 1: Baseline Characterisitics by Study Arm

Variable	B/F/TAF arm (n = 260)	CAR arm (n = 260)
Age in years, median (min, max)	64.0 (60.0, 79.0)	63.0 (60.0, 79.0)
Female sex, n (%)	124 (48%)	143 (55%)
Black race, n (%)	260 (100%)	260 (100%)
Body-mass index in kg/m², median (IQR)	25.9 (23.1, 29.4)	27.0 (23.3, 30.5)
Creatinine clearance < 60 mL/min, n (%)	111 (43%)	126 (48%)
Grade 2-4 lipid abnormality*, n (%)	129 (50%)	127 (49%)
Time on ART in years, median (IQR)	9.5 (7.2, 9.8)	9.5 (6.7, 9.7)
Currently on TDF-containing regimen, n (%)	245 (94%)	250 (96%)

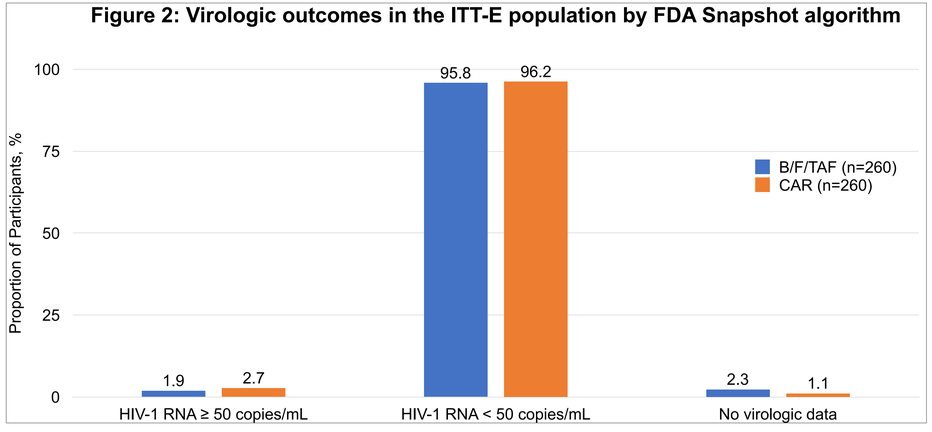
Switching to **B/F/TAF** may be an **effective and safe** strategy for **virally suppressed African adults ≥ 60 years** on a TDF-containing regimen, and may be a viable option for treatment modification in patients **at risk for osteoporosis or deterioration of renal function**

Figure 1: B/F/TAF Elderly Switch Study Design



- At week 48, 5/260 participants (1.9%) in the B/F/TAF arm and 7/260 (2.7%) in the CAR arm had HIV-1 RNA ≥50 copies/mL (difference [95% CI], -0.8% [-3.4 to 1.8]), meeting non-inferiority (Figure 2); none met the threshold for drug resistance testing (≥500 copies/ml)

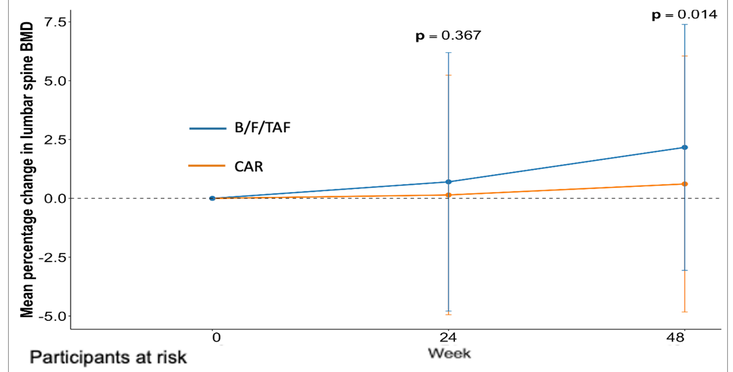
Figure 2: Virologic outcomes in the ITT-E population by FDA Snapshot algorithm



RESULTS contd…

- The mean percentage change in lumbar spine BMD was +2.17% (SD 5.23) on B/F/TAF and +0.61% (SD 5.44) on CAR (difference [95% CI], 1.56 [0.32 to 2.79], p=0.014, Figure 3)

Figure 3: Mean percentage change from baseline in lumbar spine BMD



Participants at risk	Week 0	Week 24	Week48
BFTAF group	143	142	140
Current ART	153	153	151

- Grade 3 or 4 adverse events (AEs) were uncommon (3.1% on B/F/TAF; 2.3% on CAR) with no treatment-related serious AEs
- Participants discontinuing study drug due to any AE was 1 (0.4%) on B/F/TAF and 15 (5.8%, all due to declining kidney function) on CAR

CONCLUSION

Switch to B/F/TAF was non-inferior to continuing CAR in an African population aged ≥60 years with no prior virologic failure and was associated with improvement in BMD and less need for treatment modification due to declining renal function

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CONTACT

loisea@uonbi.ac.ke

UNIVERSITY OF NAIROBI