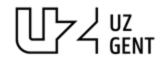
RUMBA's week 144 results confirm reassuring metabolic outcomes in both DTG/3TC and B/F/TAF.



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BACKGROUND









Other switch-studies show non-inferior virological efficacy of DTG/3TC versus 3/4 drug regimens as well as its safety and tolerability

2nd generation integrase inhibitors and tenofovir alafenamide (TAF) have been associated with weight gain



RUMBA STUDY

Phase 4 RCT

Weight

Virologic suppressed participants were 2:1 randomized to switch to DTG/3TCsor switch to ofestavison B/F/TAF



Metabolic outcomes as secondary endpoints

Fat %

Differences in metabolic outcomes betweenW144 and baseline are reported here

RESULTS

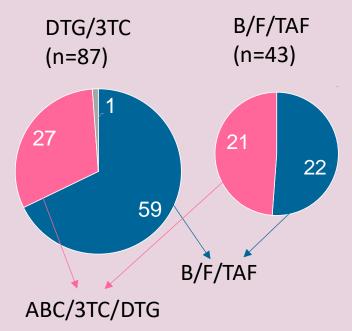
Flow diagram

Randomized: 134 ITT-E: 130 W48: 121 W144: 103

Baseline characteristics

	Total (n=130)		B/F/TAF (n=43)		DTG/3TC (n=87)	
Sex, M/F	118/12		39/4		79/8	
Ethnicity, European/African/ Other	102/14/14		32/5/6		70/9/8	
Age, y, median (IQR)	47	(37-55)	46	(38-52)	48	(40-56)
Time on ART, y, median (IQR)	7.2	(4.6-10.8)	6	(4.4-9.0)	8.6	(5.2-11.5)
BMI, kg/m², median (IQR)	25	(23-28)	25	(22-26)	26	(23-28)
<1y on 2 nd gen INSTI	15		4		11	
TAF naïve / <1y on TAF	49/11		21/4		28/7	

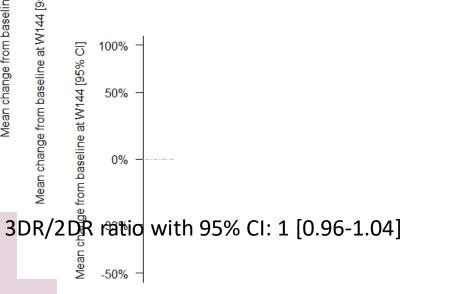
Previous regimens





RESULTS

No statistically significant differences were observed between the two arms.



3DR/2DR ratio with 95% CI: 1.04 [0.93-1.16]

3DR/2DR ratio with 95% CI: 1.05 [0.99-1.11]

3DR/2DR ratio with 95% CI: 0.93 [0.68-1.25]

3DR/2DR ratio with 95% CI: 0.98 [0.95-1.01]

3DR/2DR ratio with 95% CI: 1 [0.93-1.08]

; 8%]

RUMBA VERSUS OTHER DTG/3TC TRIALS





n=553

W48: More weight gain in B/F/TAF vs DTG/3TC (adjusted difference 0.92kg)

Mainly in subgroups switching off ABC or TDF

RUMBA: W48

More increase in fat% in subgroup switching from ABC/3TC/DTG to B/F/TAF (+4% vs. +1%)

W144: no significant changes

DYAD

n=222

W48: No differences in weight changes between DTG/3TC and B/F/TAF

Prior regimen: B/F/TAF

RUMBA: subgroup B/F/TAF as baseline regimen: W48 & W144 no differences in weight changes between DTG/3TC and B/F/TAF arm



CONCLUSIONS & CONSIDERATIONS

- RUMBAs week 48 data showed that switching to DTG/3TC had no impact on the viral reservoir. Metabolic outcomes were comparable between 2DR and 3DR, with slightly better body composition measures in 2DR [1].
- At week 144, we confirm reassuring metabolic outcomes in both the DTG/3TC and B/F/TAF group. No statistically significant differences are found.

- Metabolic outcomes in DTG/3TC switch trials depend on baseline regimen.
- Metabolic outcomes should be further investigated to better understand their role and individualize treatment in people with increased risk of metabolic comorbidity.
- We await further RUMBA W144 analyses, with multiple imputations based on all intermediate data (week 72, 96 and 120) as well as W240 data.

[1] De Scheerder MA et al. In depth analysis of the HIV reservoir confirms effectiveness and safety of DTG/3TC in a phase 4 randomized controlled switch trial (RUMBA). J Infect Dis. 2024 Sep 3:jiae405. doi: 10.1093/infdis/jiae405. Epub ahead of print. PMID: 39226296.

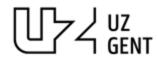
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