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LONG-TERM EFFICACY AND SAFETY OF MAINTENANCE 3-DAY-PER-WEEK SCHEDULE WITH THE SINGLE TABLET REGIMEN EMTRICITABINE/EFAVIRENZ/TENOFOVIR

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Background: Due to the long half-life of its components, we hypothesized that a maintenance schedule of 3-day-per-week efavirenz/emtricitabine/tenofovir-disoproxil-fumarate would maintain virological efficacy while reduce toxicity in the long-term.

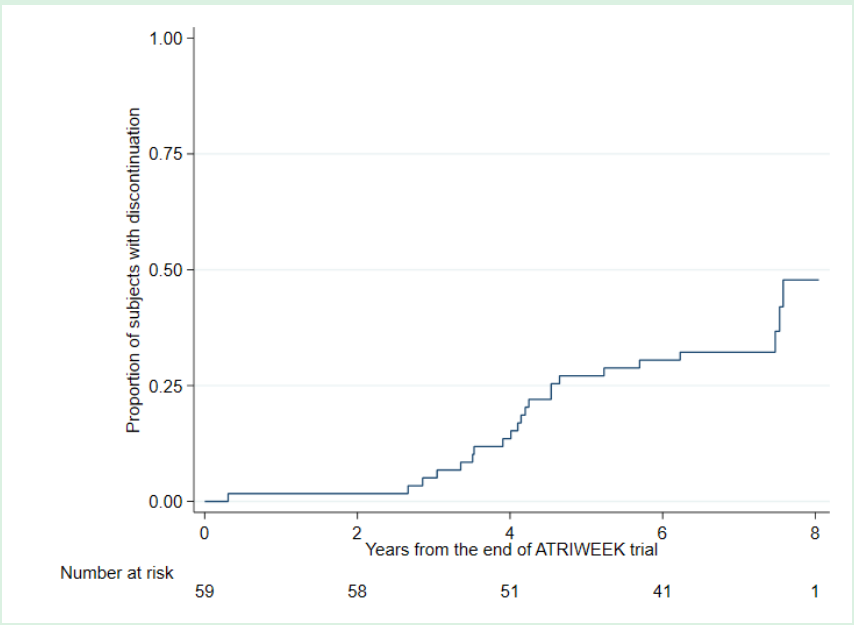
METHODS

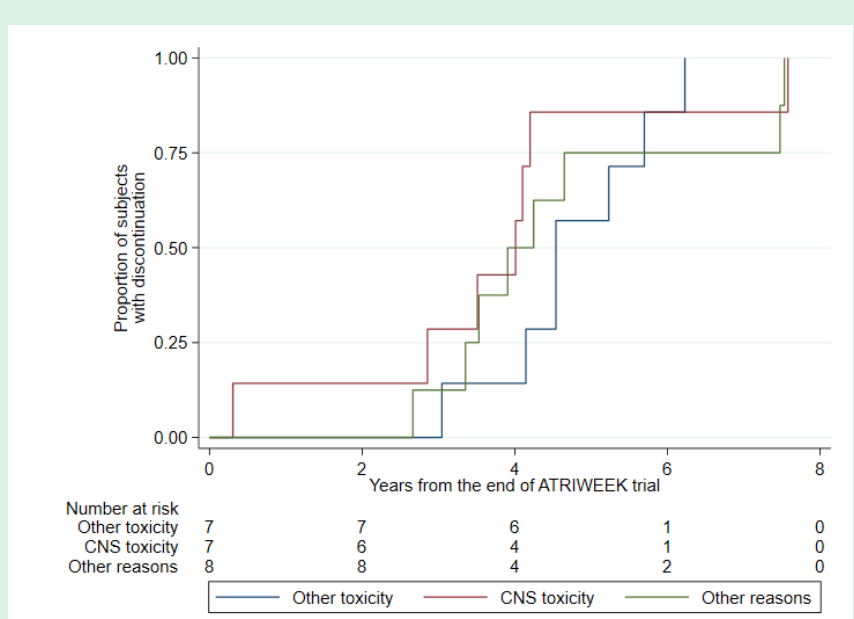
After an initial 24-week randomized phase (1), all A-TRI-WEEK trial (ClinicalTrials.gov, NCT01778413) participants were offered to switch to the 3-day-per-week strategy. HIV-RNA, CD4/CD8 cells, and blood and urine chemistries were collected every six months. Lumbar/hip bone mineral densities (BMD) were screened once a year. Treatment failure was defined as virological failure (confirmed HIV RNA ≥50 copies/mL), therapy discontinuation for any reason, or lost to follow-up. Secondary outcomes were changes in CD4/CD8 cells, plasma lipids, estimated glomerular filtration rate (eGFR, CKD-EPI), urine protein/creatinine, and lumbar/femur BMD.

RESULTS

Of 61 persons initially enrolled, 59 (97%) accepted to participate in the extension phase. Most of participants were men (n=53, 90%). Median (IQR) baseline values were: age 56 years (IQR 46-60); CD4 563 (457–697) and CD8 569 (447–703)cells/mm3; total, LDL, and HDL cholesterol 194 (168–218), 124 (117-131), and 47 (40–55) mg/dL; eGFR 94 (92-97) ml/min/1.73m2 and urine protein/creatinine 80 (59-100) mg/g; lumbar and hip BMD were 0.93 (0.90-0.96) and 0.96 (0.93-0.99) g/cm2, respectively.

After a median of seven years of follow-up, 37 persons (62%) remained free of treatment failure. Twenty-two (37%) persons discontinued antiretroviral regimen due to: persistent CNS symptoms (n=7), decreasing bone mineral density (n=7), risk of interactions (n=2), preference for other regimens (n=2) and neoplasia, virological failure, non-availability of medication due to travel, and death (end-stage liver disease, unrelated to antiretroviral therapy). Median (IQR) CD4 and CD8 changes at 7 years were +91 (31-151) and +125 (53-197) cells/mm3. Total, LDL, and HDL cholesterol remained stable over time. Triglycerides, eGFR, urine protein/creatinine, and lumbar and hip BMD showed a bimodal curve with stable values in the first half of follow-up, and increases (triglycerides, urine protein/creatinine) or decreases (eGFR and BMD) in the second half of follow-up. Seventy-five percent of discontinuations occurred in the second half of follow-up.





CONCLUSIONS

3-day-per-week efavirenz/emtricitabine/tenofovir-disoproxil-fumarate as a maintenance therapeutic strategy was effective in the long-term and deferred toxicity.

1. Rojas J, Blanco JL, Sanchez-Palomino S, Marcos MA, Guardo AC, Gonzalez-Cordon A, et al. A maintenance 3-day-per-week schedule with the single tablet regimen efavirenz/emtricitabine/tenofovir disoproxil fumarate is effective and decreases sub-clinical toxicity. AIDS [Internet]. 2018 [cited 2022 Mar 28];32(12):1633–41. Available from: https://pubmed.ncbi.nlm.nih.gov/29746294/