RAPID INITIATION OF ANTIRETROVIRAL THERAPY WITH BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE IN A TERTIARY HOSPITAL IN BARCELONA, SPAIN. A PROSPECTIVE CLINICAL TRIAL

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BACKGROUND

Rapid initiation of antiretroviral therapy (ART) after HIV diagnosis confers individual and global public health benefits [1-2].
Some regimens chosen might have limitations.
BIC/FTC/TAF is a recommended regimen for rapid initiation due to its efficacy, high-genetic barrier, safety, simplicity, and lack of major interactions and restrictions.

PATIENTS AND METHODS

Prospective, 48-week, single-center, single-arm, proof-of-concept trial enrolling HIV-positive, ART-naïve adults referred to or diagnosed at our hospital.
BIC/FTC/TAF was started within the first week prior to laboratory tests results.
Clinical assessment and blood tests were obtained at baseline and at 4, 12, 24 and 48 weeks.
Dual-X-absorptiometry scans were performed at baseline and 48 weeks

Primary Endpoint

Proportion of patients with some of the following characteristics that made them non-eligible to receive other early ART regimen than BIC/FTC/TAF :

- CD4 <200 cells/mm^3
- VL >10^{5}copies/mL
- Positive HLA B*5701
- Positive Hepatitis B surface Antigen (HBsAg)
- Major genotypic resistance mutations
- Low bone mineral density (BMD)
- Framingham risk score (FRS) >10%
- Red flag drug-drug interactions of baseline medications
- Kidney disease (eGFR ≤50mL/min)

Secondary Endpoint

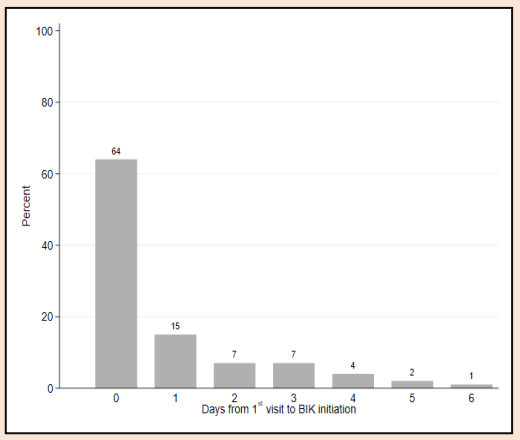
- Proportion of patients who start BIC/FTC/TAF from day 0 to day 7
- Proportion of patients with HIV VL < 50 cp/ml at week 4,12,24 and 48
- Changes in CD4 and CD8 count and CD4/CD8 ratio at week 24 and 48
- Changes in senescence response at week 24 and 48
- Proportion of patients who attend all the study visits
- Changes in subclinical obesity using dual X-ray absorptiometry at w. 48

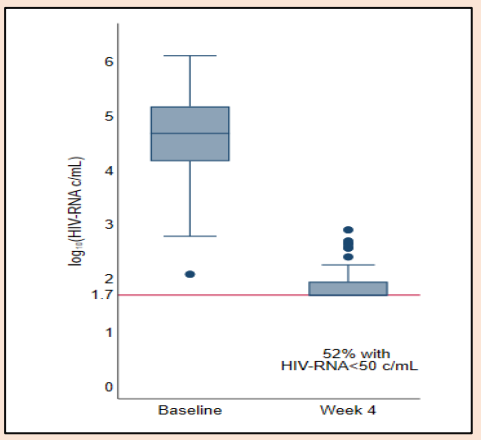
RESULTS

	N=100
Age, median (IQR)	32 (27-38)
Men, n	79
Women cis	5
trans	16

Place of Birth	N=100
Europe	34
Latin America	64
Asia	1
Africa	1

Baseline characteristics evaluated in primary outcome	n=100
CD4 count < 200 cells/mm^3	21%
HIV VL > 10^5 copies/ml	32%
Positive HBsAg	1%
Positive HLAB*5701	1%
not assessed	4%
HIV RNA genotype with major mutations (all RT 103N)	9%
not assessed	3%
Low bone mineral density (T-score in femur < 1)	46%
Framingham risk score > 10%	10%
Red-flag drug-drug interactions	3%
eGFR < 50 ml/min	0%
Total of patients that have at least one characteristic	**72%**





CONCLUSIONS

BIC/FTC/TAF for rapid treatment initiation is feasible and safe.
72% of participants had at least one baseline characteristic that would have precluded or not recommended the use of some other ART.

1. Ford N et al. Benefits and risks of rapid initiation of antiretroviral therapy. AIDS. 2018;32(1):17–23.
2. Pilcher CD e al. The effect of same-day observed initiation of antiretroviral therapy on HIV viral load and treatment outcomes in a US public health setting. J Acquir Immune Defic Syndr. 2017;74(1):44–51