

BICNOW -Clinical Trial: PRELIMINARY RESULTS OF RAPID TEST AND TREAT BIC/FTC/TAF STUDY IN NAÏVE PLHIV.

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Background: The global HIV epidemic is still not under control, even in high-income countries. To reduce the number of new diagnoses, several strategies have been implemented, including pre-exposure prophylaxis (PrEP) or rapid initiation (test and treat) of antiretroviral therapy (ART). The single-tablet regimen BIC/FTC/TAF is an ideal drug for rapid initiation. We present the preliminary data (baseline and 24 week) from the BIC-NOW trial.

Patients/methods: In this Phase IV, multi-center, open label, single-arm, 48-week study, adult participants were enrolled from Dec 2020 to Jun 2022 with follow-up through 48 weeks (w) at baseline, 4, 24, and 48w. Adherence to treatment was assessed using the SMAQ questionnaire. The EudraCT number: 2019-003251-11.

Results:

Table 3. Analytical and anthropometric data (baseline and 24w)

Table 1. Baseline data of population	n= 160
Age (year), mean (± SD)	35.7 (10.5)
Male, n (%)	144 (90)
Test and treat, n (%)	160 (100)
- ARV from the 1st day, n (%)	158 (98.8)
CD4 Nadir, mean (± SD)	395.2 (242.9)
Baseline Viral Load HIV, log ₁₀ , median (IQR)	5.6 (6.2)
- CV> 100.000 cop/mL	75(46.8)
Baseline CD4, (cel/uL), mean (± SD)	395.2
- CD4< 200 cel/uL, n (%)	36(22.5)
Baseline CD4/CD8 quotient, mean (± SD)	0.42 (0.29)
History of AIDS (A3, B3, C), n (%)	37 (23.1)
HBV co-infection, n (%)	1 (0.6)
IgG HCV positive, n (%)	8 (5)
Smoking, n (%)	62 (38.8)
Risk factor for HIV infection, n(%)	
- Heterosexual	38 (23.9)
- MSM	118 (74.2)
- Ex-IVDU	1 (0.6)
- Other	1 (0.6)

	Baseline	24 Weeks	P value
CD4 (cél/uL), mean ± SD	393± 246,9	589.8±352.7	0.0001
CD4/CD8 ratio, mean ± SD	0.43±0.29	0.7±0.5	0.0001
Creatinine clearance (mL/h), mean± SD	110±15.03	102±20.5	0.0001
Total cholesterol (mg/dL), mean ± SD	159.3±38.3	168.5±38.3	0.006
HDL cholesterol (mg/dL), mean ± SD	41.2±10.3	47.2±9.9	0.0001
LDL cholesterol (mg/dL), mean ± SD	105.6±54.2	107.8±31.6	0.053
TC/HDL ratio, mean ± SD	6.1±12.2	3.9±1.07	0.013
Triglycerides (mg/dL), mean ± SD	106.2±49.9	107.8±57.5	0.9
Bilirubin (mg/dL), mean ± SD	0.6±0.2	0.6±0.3	0.794
GPT (UI/dL), mean ± SD	42.4±61.7	23.1±12.4	0.003
GGT (UI/dL), mean ± SD	43.6±65.6	28.9±28.2	0.01
FA (UI/dL), mean ± SD	80.7±48.1	74.1±24.8	0.85
Weight (Kg), median (IQR)	73.5 (65,7-83)	76 (67.8-87.1)	0.0001
Body mass index, median (IQR)	24.3 (21.5-26.3)	25 (23-27)	0.0001
Abdominal circumference (cm), median (IQR)	85 (78-94)	90 (81-95)	0.001

Table 2. Outcomes at 24 weeks	N=160
Intention-to-treat analysis (ITT)	
- VL< 50 copies, n (%)	142 (88.8)
- VL < 100 cop/mL, n(%)	160 (100)
Dropped treatment, n (%)	0
Fogertfulness, doses pills, n (%)	0
Adverse events, n (%)	
- Grade3-4	0
-Adverse events leading to drug withdrawal	0

Conclusions: BIC//FTC/TAF is a suitable option for the rapid initiation of ART in naïve individuals infected with HIV. Treatment was associated with a rapid reduction in viral load, significant increase in CD4 count, and, as expected in ART-naïve patients, a small increase in weight, BMI, abdominal circumference and some lipid components, but TC/HDL ratio decreased. This study was funded by Gilead Sciences. Investigator Sponsored Research ISR-ES-19-10727