Multicentre, prospective cohort study of same-day initiation of antiretroviral therapy with BIC/FTC/TAF among antiretroviral-naïve people with HIV

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Background

Taiwan has implemented same-day ART initiation after introduction of immunochromatography (ICT) to expedite the confirmation of HIV diagnosis since 2021. This ongoing multicentre, prospective cohort study aimed to investigate the clinical outcomes of people with HIV (PWH) who initiated coformulated bictegravir (BIC), emtricitabine (FTC), and tenofovir alafenamide (TAF) (BIC/FTC/TAF) within 24 hours of confirmed HIV diagnosis.

Materials and Methods

Study period: January 2021 – December 2023
Study design: single-arm interventional feasibility trial
Intervention: Bictegravir/Emtricitabine/Tenofovir Alafenamide
Inclusion criteria: Patients who test positive by HIV screening tests (4th generation Ag/Ab) by clinical care providers or by VCT counselors within 3 days of Visit 1; aged 20 years or older
Exclusion criteria: Prior HIV diagnosis, prior ART for HIV infection, CKD stage ≥4 or receiving dialysis, severe hepatic impairment (Child-Pugh score C), active or latent TB infection or clinical apparent central nervous system infection, pregnancy or breastfeeding, allergy to FTC or TDF containing medication
ClinicalTrials.gov ID: NCT04712058

Study Outcomes

Primary endpoints:

1. Proportions of retention in care at Week 48
2. Proportions of viral suppression (<50 copies/ml) at Week 48*

Secondary endpoints:

1. Rate of acceptance of same-day initiation among PWH received a confirmed diagnosis of HIV infection
2. Viral suppression <200 copies/ml at Week 1, 4, and 48*
3. Adverse effect at Week 4 and Week 48

*ITT analysis using FDA Snapshot algorithm and observed analysis (on BIC/F/TAF with last-observation carried forward imputation) were both performed.

Table 1. Demographics and baseline characteristics

	N= 225
Age, years, median, (IQR)	32.5 (27.7-38.8)
Sex at birth, male, n (%)	217 (96.4)
Weight, Kg, median (IQR)	66.9 (60.0-75.0)
BMI, kg/m^2, median (IQR)	22.3 (20.7-25.1)
HIV risk factors, n (%) GBMSM/ IVDU/ Other	221 (93.8)/ 13 (5.8) / 1 (0.4)
Baseline HIV RNA, log10 copies/ml >100,000, n (%) >1,000,000, n (%)	5.2 (4.7-5.9) 140/222 (63.1) 50/222 (22.5)
Baseline CD4 counts, mm^3 <200, n (%) 200-349, n (%) 349-499, n (%) ≥500, n (%)	271 (108-391) 75/215 (34.9) 71/215 (33.0) 42/215 (19.5) 27/215 (12.6)
HBV coinfection, n (%)	7/222 (3.2)
AIDS-defining illness, n (%)	36/225 (16.0)
Delay between inclusion and initiation of ART (>1 day), n (%)	2 (0.9)
Duration from first screening to ART, days, median (IQR) Same-day, n (%) 1-7 days, n (%) > 7 days, n (%)	0 (0-1) 131/221 (59.3) 88/221 (39.8) 2/221 (0.9)

Results

During the 3-year study period, 225 newly diagnosed PWH (median age, 32.5 years, IQR 27.7-38.8) were enrolled (Table 1); 96.4% were male, and 94.2% were GBMSM. Of all participants, 34.9% presented with CD4 counts <200 cells/mm^3. There were 63.1% had PVL >100,000 copies/ml and 22.5% >1,000,000 copies/ml. All participants accepted the study drug (BIC/F/TAF) and only 2 (0.9%) initiated 1 day after diagnosis. As of October 2024, 219 participants (97.3%) had completed 48 weeks of observation. Among them, 18 (8.2%) patients had dropped out from the study and 201 (91.8%) were retention in care at Week 48. The virological outcomes were shown in Table 2, including an exploratory subgroup analysis of participants with high viral loads.

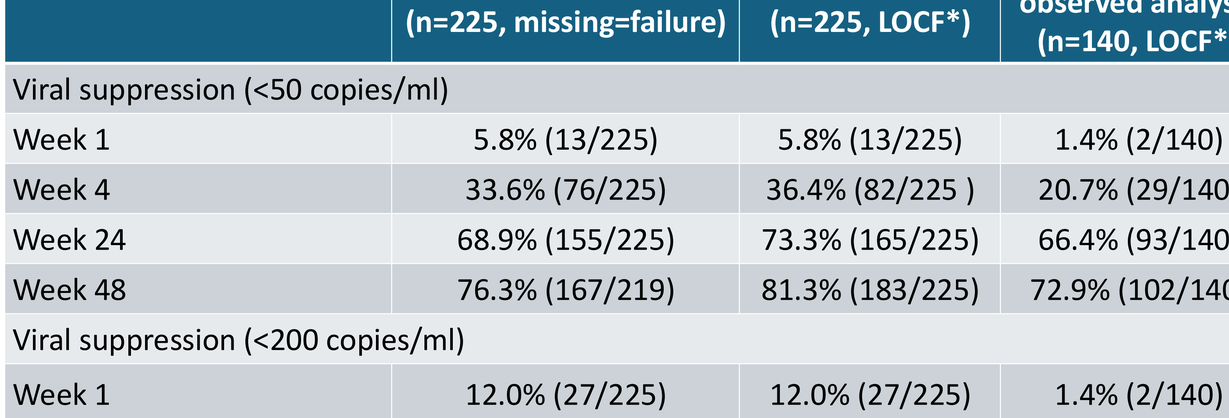
In ITT analysis using FDA Snapshot algorithm of Week 48, 76.3% (167/219) had viral suppression (<50 copies/ml), 16.7% (35/219) had RNA load ≥ 50 copies/ml, and 8.7% (17/219) had no virological data. Only six participants (2.7%) had viral load ≥ 200 copies/ml and 196 (89.5%) had PVL <200 copies/ml. Among those without virological data, 8 (3.7%) were still engaged in care, 2 (0.9%) have discontinued study drug due to skin rash, and 7 (3.2%) had discontinued study due to other reasons. In observed analysis (with last observation carried forward imputation for missing data), 81.3% had PVL lower than 50 copies and 96.4% lower than 200 copies at Week. No study-drug related severe adverse events was observed in this study.

Table 2. Virological outcomes at Week 1, 4, 24, and 48

	ITT analysis (n=225, missing=failure)	Observed analysis (n=225, LOCF*)	High viral load (10^5) observed analysis (n=140, LOCF*)
Viral suppression (<50 copies/ml)			
Week 1	5.8% (13/225)	5.8% (13/225)	1.4% (2/140)
Week 4	33.6% (76/225)	36.4% (82/225)	20.7% (29/140)
Week 24	68.9% (155/225)	73.3% (165/225)	66.4% (93/140)
Week 48	76.3% (167/219)	81.3% (183/225)	72.9% (102/140)
Viral suppression (<200 copies/ml)			
Week 1	12.0% (27/225)	12.0% (27/225)	1.4% (2/140)
Week 4	65.8% (148/225)	68.9% (155/225)	57.9% (81/140)
Week 24	85.8 (193/225)	93.8% (212/225)	92.1% (129/140)
Week 48	89.5% (196/219)	96.4% (217/225)	95.7% (134/140)

*LOCF: last-observation carried forward

Figure 1. ITT-FDA Snapshot (<50 copies/ml) at Week 24 and Week 48



*FDA Snapshot algorithm, missing and drug switch are considered failure; AE, adverse events; VL, viral load

Conclusion

This study demonstrated the feasibility of same-day initiation with BIC/F/TAF in ART naïve PWH, including a substantial proportion of PWH with high baseline viral loads, 76% were able to achieve PVL <50 copies/ml at week 48. No BIC/F/TAF-related severe AEs were observed.

*This study is an investigator-sponsored research study, initiated and led by the principal investigator, received financial and material support from Gilead Sciences. The investigators retains full autonomy over its design, execution, and interpretation.