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RESEARCH ARTICLE

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A randomised control trial of BIC/F/TAF vs DRV/c/F/TAF in context of HIV test-and-treat, BicTnT

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ABSTRACT

Background: Head-to-head data for bictegravir/emtricitabine/tenofovir alafenamide (BIC/F/TAF; B) and darunavir/cobicistat/emtricitabine/tenofovir alafenamide (DRV/c/F/TAF; D) are lacking in the context of rapid antiretroviral therapy (ART) initiation. This study, BIC-T&T, evaluates the efficacy and tolerability of B vs D in a UK test-and-treat setting.

Setting: BIC-T&T was a randomised, open-label, multi-centre, study in which participants initiated ART within 14 days after confirmed HIV-1 diagnosis before baseline laboratory.

Methods: The primary endpoint is the virological response (HIV RNA < 50copies/mL) at week 12 by time-weighted average change in $\log_{10}$ HIV RNA recorded in viral load assays from treatment initiation to week 12, using two-sample Wilcoxon rank-sum test.

Results: 36 participants were randomised: 94% were male, 53% white; mean (SD) age was 35 years (11.8). Baseline mean (±SD) $\log_{10}$ HIV-RNA was 4.79 (± 0.87) $\log_{10}$ copies/mL and CD4 505 (±253) cells/mm^3. The mean (±SD) time from confirmed HIV diagnosis to ART initiation was 7.9 (± 3.7) days. The time-weighted mean decrease in $\log_{10}$ HIV RNA from treatment initiation to week 12 was significantly greater in B in comparison to D (3.1 vs. 2.6 $\log_{10}$ copies/mL, $p < 0.001$). Both regimens demonstrated good tolerability with infrequent laboratory abnormalities and no grade 3 or 4 adverse events.

Conclusion: In this first head-to-head study in the context of ART initiation, HIV RNA decline from baseline to week 12 was significantly more rapid for BIC/F/TAF compared with DRV/c/F/TAF.

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DRV/c/F/TAF, BIC/ftc/taf, HIV infection, rapid ART strategy, test-and-treat

Background

The use of antiretroviral therapy (ART) in people living with HIV (PLHIV) has been associated with a dramatic reduction in AIDS-related morbidity and mortality as well as non-AIDS-related serious events [1].

The key to successful HIV drug treatment is adherence to the prescribed combination every day. The approval of single tablet regimens (STRs) provides HIV care providers with a 'one tablet once a day' therapy, making adherence much easier for patients [2].

The British HIV Association and other guidance recommends that initiation of ART should be offered to all individuals living with HIV within 2–4 weeks of diagnosis. Guidance also suggests the pros and cons of same-day ART initiation should also be discussed with each individual and recommended in primary HIV infection [2].

Delays in time to ART initiation often occur due to waiting for baseline blood test results; in particular HIV genotype, CD4 count, opportunistic infection screen and provision of a clinical review [3].

Where rapid ART initiation or 'test-and-treat' (within seven days from confirmed diagnosis) is recommended and desired by the patient, national guidelines recommend using the following core agents: boosted protease inhibitors (bPI) or a high genetic-barrier unboosted integrase inhibitor (INSTI) such as dolutegravir or bictegravir [2,4,5].bPI are associated with a higher potential for drug interactions as well as short and long term toxicities, of note abnormal

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liver function, which can often be deranged in acute infection with high HIV viraemia, that could be avoided if other less toxic third agents are prescribed [2,6,7]. Moreover, viral decay is slower with bPI compared to integrase inhibitors [8]: an issue of particular importance amongst newly acquired HIV-positive individuals at risk of onward viral transmission [9]. Furthermore, with minimal transmitted drug resistance, the need to prescribe bPI as initial therapy in a clinical context when the resistance test is not yet available has been negated by the advent of high genetic-barrier unboosted integrase inhibitors [10].

Head-to-head data for BIC/F/TAF (B) and DRV/c/F/TAF (D) are lacking in the context of rapid ART initiation. This study, BIC-T&T, evaluated the efficacy and tolerability of both regimens in a UK test-and-treat setting.

Setting

The trial is an open-label, two arm, phase IIIb, multicentre study in antiretroviral naive subjects diagnosed with HIV infection.

Inclusion criteria

Adult aged 18 years or over with a confirmed HIV-1 diagnosis less than 14 days before ART initiation.

Exclusion criteria

1. People with a uterus who are planning pregnancy, pregnant or breast/chest-feeding.
2. Use of medications known to interact with study drugs
3. Taking HIV post-exposure prophylaxis

The study was reviewed and approved by the South East London NHS Research Ethics Committee (Project ID 19/LO/1953) and by local regulatory bodies. The clinical trial was registered at ClinicalTrials.gov (NCT04653194).

Participants were recruited at three UK sites (56 Dean Street, Chelsea and Westminster NHS Foundation Trust; Wharfside clinic, St Mary's Hospital, Imperial College Healthcare NHS Trust; Lawson Unit, Royal Sussex County Hospital, Brighton & Sussex University Hospitals NHS Trust) after HIV diagnosis was confirmed.

Methods

Study protocol

Following written informed consent, subjects were randomised at baseline in a 1:1 ratio to receive either bictegravir/emtricitabine/tenofovir alafenamide (BIC/F/TAF; B) one pill once daily or darunavir/cobicistat/emtricitabine/tenofovir alafenamide (DRV/c/F/TAF; D) one pill once daily for the treatment of HIV within 14 days of confirmed HIV diagnosis before baseline laboratory results were available. Randomisation was performed using a computer package (Sealed Envelope, London, UK).

All baseline (day 1) tests were completed prior to the administration of the first dose of the study drug. ART initiation took place within 48 h after the baseline visit. The study duration was 48 wk for each participant with study visits at baseline, week 1, 2, 4, 12, 24, and 48.

Outcomes

The primary endpoint was the time-weighted average change from baseline in $\log_{10}$ HIV RNA level at 12 wk (+/− 1 week) using two-sample Wilcoxon rank-sum test. Week 12 was chosen as integrase inhibitors have been shown to achieve viral suppression in a significant proportion of individuals starting these regimens with an undetectable viral load within three months of antiretroviral initiation.

Secondary endpoints were: (i) absolute efficacy of study treatments: proportion of patients treated with each study drug with HIV viral load less than 50 copies/ml at week 2, 4, 12, 24, and 48; (ii) safety and tolerability up to week 48 measured as occurrence of changes in laboratory parameters and occurrence of adverse events (AEs), severity of AEs and occurrence of treatment discontinuations due to tolerability of treatments [11].

Exploratory markers included quantification of proviral DNA load and comparison of the results and their changes over time between both study arms. HIV proviral load was quantified using an in-house, semi-nested PCR to quantify HIV integrase DNA.

Sample size

Using the primary endpoint of the time-weighted average change from baseline in $\log_{10}$ HIV RNA level through 12 wk, the planned sample size was 36 patients (18 per arm). This provides 80% power to establish non-inferiority with an upper limit of 0.5

log10 HIV RNA copies/mL for the two-sided 95% CIs, assuming a common standard deviation of 0.5 log_{10} copies/mL and allowing for a 10% lost-to-follow-up.

Results

Between September 2020 and April 2022, 36 participants were randomised: 19 to arm B and 17 to arm D. One individual was not randomised due to concomitant medication being associated with an exclusionary drug-drug interaction.

At week 12, 3 (8%) participants had withdrawn, all in arm D (2 lost to follow-up; 1 unable to make study visits). At week 48, 6 participants (17%) were lost to follow-up (2 in arm B and 4 in arm D).

Baseline characteristics of the 36 randomised participants are shown in Table 1. 94% were male, 53% white; mean (SD) age was 35 (11.8) y. Baseline mean (±SD) log_{10} HIV-RNA was 4.79 (±0.87) log_{10} copies/mL and CD4 505 (±253) cells/mm^3. The mean (±SD) time from confirmed HIV diagnosis to ART initiation was 7.9 (± 3.7) days. Baseline resistance tests failed to amplify in one participant. Of the 35 resistance tests available, 11 (31%) demonstrated any major resistance mutation according to the Stanford database [12].

Figure 1 shows the decrease in the log_{10} HIV-RNA viral load from baseline until week 48 according to each randomised arm. The time-weighted mean decrease in log_{10} HIV RNA from treatment initiation to week 12 was significantly greater in B in comparison to D (3.1 vs. 2.6 log_{10} copies/mL, $p < 0.001$).

Figure 2(A) shows the proportion of patients with HIV viral load less than 50 copies/ml at week 2, 4, 12, 24, and 48 according to each randomised arm (observed analysis).

Figure 2(B) shows the numbers for each week including those with no viral load data.

Participants in Arm B attained viral suppression more quickly after baseline than in Arm D. In ITT analysis, at week 12, 84% (16/19) were suppressed in Arm B versus 35% (6/17) in Arm D ($p < 0.05$). At week 48, the 74% (14/19) were suppressed in Arm B versus 65% (11/17) in Arm D.

Thirty-four (94%) participants reported at least one adverse event (AE) (Table 2). Most common AEs were infections and infestations (mostly sexual transmitted infections) and gastrointestinal disorders. Twenty-two individuals experienced drug-related AEs, 13 in arm B and 9 in arm D. Two individuals experienced serious AEs: one had latent tuberculosis and one DRESS syndrome, neither determined to be related to the study drugs.

Eight participants experienced at least one grade 3 laboratory abnormality (3, arm B; 5, arm D); there were no grade 4 laboratory abnormalities (Table 2). None of the laboratory abnormalities were determined to be related to the study drugs.

Mean CD4 counts rose in both arms from baseline to week 48: 452 cells/mm^3 to 634 cells/mm^3 (Arm B) and 568 cells/mm^3 to 818 cells/mm^3 (Arm D).

Table 1. Baseline demographics of 36 participants in BIC-T&T trial, according to randomised arm.

Baseline characteristic	Total	BIC/F/TAF (Arm B)	DRV/c/F/TAF (Arm D)
N	36	19	17
Age (y) (mean, SD)	35 (11.8)	34 (13.7)	37 (9.4)
Gender (male:female)	34:2	19:0	15:2
Ethnicity (*n*, %)			
White	19	11	8
Hispanic	4	2	2
Black	6	2	4
Asian	4	3	1
Other	3	1	2
Log_{10} HIV-RNA (log_{10} copies/mL) (mean, SD)	4.79 (0.87)	4.86 (0.71)	4.71 (1.03)
CD4 (cells/mm^3) (mean, SD)	505 (253)	452 (254)	568 (246)
Time to start ART (d) (mean, SD)[a]	7.9 (3.7)	7.7 (3.4)	8.1 (4.0)
Transmitted genotypic resistance[b]			
Any major	11	2	9
NNRTI	7	1	6
NRTI	5	1	4
PI	1	0	1
INSTI	0	0	0

BIC/F/TAF,B, Bictegravir/emtricitabine/tenofovir alafenamide; DRV/c/F/TAF,D darunavir/cobicistat/emtricitabine/tenofovir alafenamide. SD, standard deviation; ART, anti-retroviral therapy; NNRTI, non-nucleotide reverse transcriptase inhibitor; NRTI, nucleotide reverse transcriptase inhibitor; PI, protease inhibitor; INSTI, integrase inhibitor. [a]Time from confirmed HIV diagnosis to ART start. [b]Presence of any major integrase, reverse transcriptase or protease mutations consistent with transmitted drug resistance determined using the Stanford HIV resistance database. In arm B, one resistance test failed to amplify. The following mutations were seen: NRTI: D67G ($n = 1$); NNRTI: K103N ($n = 1$). In arm D, the following mutations were seen: PI: V82A ($n = 1$); NRTI: M184V ($n = 3$), D67N ($n = 1$), K219Q ($n = 1$); NNRTI: K103N/Q ($n = 3$), V179D/E ($n = 2$), E138A ($n = 1$). Some individuals demonstrated more than one mutation.

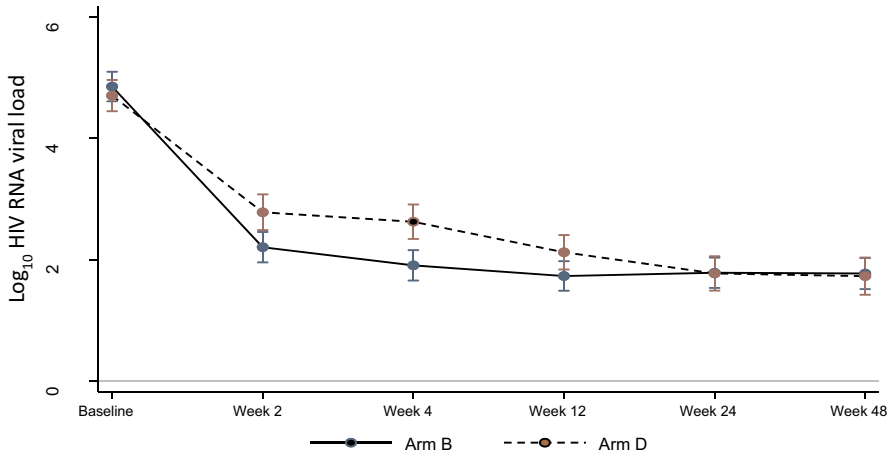
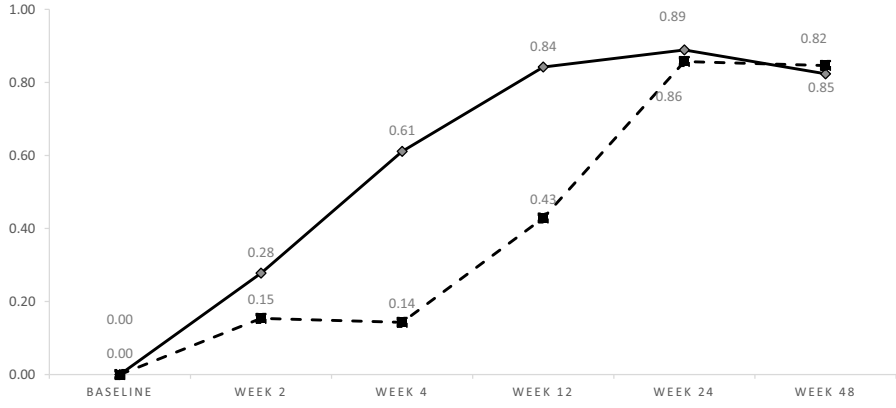


Figure 1. The decrease in the log_{10} HIV-RNA viral load from baseline until week 48 according to each randomised arm (arm B, solid line; arm D, dashed line).



	HIV-1 RNA	Baseline	Week 2	Week 4	Week 12	Week 24	Week 48
Arm B	>50 cpm	19	13	7	3	2	3
	<50 cpm	0	5	11	16	16	14
	No data	0	1	1	0	1	2
Arm D	>50 cpm	17	11	12	8	2	2
	<50 cpm	0	2	2	6	12	11
	No data	0	4	3	3	3	4

Figure 2. (A) The proportion of patients with HIV viral load (HIV-1 less than 50 cpm (copies/ml) at baseline, week 2, 4, 12, 24, and 48 according to each randomised arm by observed analysis (arm B, solid line; arm D, dashed line). (B) HIV viral load (HIV-1 RNA) at baseline, week 2, 4, 12, 24, and 48 according to each randomised arm.

In terms of exploratory markers, there was no difference in between arms in proviral DNA load at baseline, at week 48 or the percentage reduction in proviral DNA load between baseline and week 48.

Conclusion

In this first head-to-head study in the context of rapid ART initiation, HIV RNA decline from baseline to week 12 was significantly faster for BIC/F/TAF compared with DRV/c/F/TAF. By week 48, there was no significant difference in the proportion of individuals who were virally suppressed.

Both arms demonstrated good tolerability with no grade 3 or 4 AEs and infrequent laboratory abnormalities.

Hence the advantage of BIC/F/TAF over DRV/c/F/TAF in ART-naïve individuals diagnosed with ART is the ability to quickly achieve viral suppression and decreases the risk of onward transmission of HIV at a time of high viral load, particularly in the first 12 wk after HIV diagnosis [13].

During 2021–2022, a large multi-centre randomised controlled trial in China randomised adult MSM to initiate either BIC/F/TAF or efavirenz/lamivudine/tenofovir within 14 days of HIV diagnosis. At week 48, individuals randomised to BIC/F/TAF

Table 2. Summary of individuals who experienced clinical adverse events and laboratory abnormalities up to week 48 according to study drug according to randomised arm.

Baseline characteristic (*N*)	BIC/F/TAF (Arm B)	DRV/c/F/TAF (Arm D)
N	19	17
Any AE	19	15
Drug-related AE	13	9
Serious AE[a]	2	1
Most common AEs (incidence >=10%)		
Infections and infestations	13	13
Gastrointestinal disorders	9	7
Psychiatric disorders	5	4
Nervous system disorders	5	3
Skin and subcutaneous tissue disorders	3	5
Respiratory, thoracic and mediastinal disorders	2	4
Investigations	5	1
Surgical and medical procedures	1	5
Laboratory abnormalities, grade 3[a]		
Estimated GFR	1	1
Total Cholesterol	1	1
Triglycerides	1	0
LDL	0	2
Glucose	1	2

BIC/F/TAF, Bictegravir/emtricitabine/tenofovir alafenamide; DRV/c/F/TAF, darunavir/cobicistat/emtricitabine/tenofovir alafenamide. *N*, number; AE, adverse event. [a]No serious AEs or laboratory abnormalities were assessed to be related to either IMP on this trial.

had better retention in care, viral suppression and lower incidence of adverse events [14]. The Rainbow study from Rome, Italy initiated BIC/F/TAF to a cohort of 30 individuals within 7 days of HIV diagnosis with advanced disease. Their results also support the feasibility, efficacy and safety of this regimen in the context of rapid ART initiation [15].

In addition, single-arm studies in test-and-treat settings have demonstrated the feasibility, efficacy and safety of using single-tablet regimens: dolutegravir/lamivudine (STAT study) and DRV/c/F/TAF (DIAMOND study) [16,17].

LAPTOP, an ongoing head-to-head randomised controlled trial of the same study drugs as this trial in individuals with diagnosed with advanced HIV infection will also provide further valuable information on both drugs [18].

Although not typically used, the primary hypothesis was chosen, and an appropriate power calculation performed, in order to demonstrate the difference in the ability of both drugs to achieve viral suppression by week 12. Although this is an entirely expected finding, we feel that it is useful to have this demonstrated in a head-to-head study in a test-and-treat setting.

The presence of baseline resistance mutations is higher than expected at 31%. In the UK, the prevalence is expected to be less than 10% [19]. The reason for this is unknown although the majority of mutations are polymorphisms and all participants demonstrated full genotypic susceptibility to the study drugs.

Limitations include the finding that the number of participants lost-to-follow-up was larger than expected. This is likely to reflect the population recruited from the three clinics in large urban centres (mostly London) and the fact that the study took place over COVID-19 lockdowns, making clinic attendance more difficult for participants than previously. However, despite this, the primary objective was still able to show a significant difference between the two arms.

The population recruited to this study was from the UK only and predominantly white males aged 30–40 years with high baseline CD4 counts, reflecting the demographics of individuals newly diagnosed with HIV at the recruiting sites. We are mindful that this may not reflect the populations served in other UK settings or elsewhere.

Unlike the studies discussed earlier, the fact that this a small, open-label study with a larger drop-out rate limits our ability to comment on the safety of both drugs and the generalisability of the findings.

The mean time from confirmed HIV diagnosis to ART initiation was 7.9 days, a little over 1 week. Recruitment during the COVID-19 pandemic may have prolonged this time-period. However, this was well within the 14 days set out on the protocol. This trial demonstrates that the offer of ART sooner than 2–4 weeks after a diagnosis of HIV stated in UK guidance with either of the two STRs studied is feasible and acceptable, although the lack of retention in the study is of concern.

Disclosure statement

GW has received travel and research grants from and has been an advisor/speaker for ViIV and Gilead. SF reports that their department receives funding for research from

Gilead, ViiV, AbbVie but none is to them personally. AC has received research contracts from ViiV, Gilead, MSD, GSK, travel grants from ViiV and Gilead, has been an advisor to ViiV and Gilead and a speaker for MSD. AM worked for Chelsea and Westminster NHS Foundation Trust during the study period but now works for ViiV. MH has received travel grants and been a speaker for Gilead. IJ reports research grants from Chelsea and Westminster Hospital NHS Foundation Trust Research and Development. AK reports research grants from Chelsea and Westminster Hospital NHS Foundation Trust Research and Development and from Gilead. GT reports grants from Chelsea and Westminster Hospital NHS Foundation Trust Research and Development and from National Institute for Health and Care Research Imperial Biomedical Research Centre, during the conduct of the study. MB has received travel and research grants from and has been advisor/speaker for Janssen, ViiV, MSD, Pfizer, Gilead, Cipla, GSK, AZ. All other authors: none to declare.

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