A summary of the final results of a study comparing B/F/TAF and DTG + F/TDF treatment in adults with both HIV and HBV who had not been treated previously

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This is a plain language summary of a scientific presentation that was originally presented by Dr Anchalee Avihingsanon at IAS 2023, the 12th IAS conference on HIV Science (E-poster). This plain language summary only presents selected data and is not intended to replace the full presentation. Please refer to the presentation slides (available by QR code at the end of this document) for full details. The intended audience for this plain language summary is registered conference attendees.

Background

Tenofovir alafenamide (TAF) and tenofovir disoproxil fumarate (TDF) are medicines used to treat hepatitis B virus (HBV). They are also used to treat HIV as part of combination therapies like B/F/TAF and DTG + F/TDF.

B/F/TAF is a combination of 3 drugs in a single pill to treat HIV. The 3 drugs are bictegravir, emtricitabine and tenofovir alafenamide. DTG + F/TDF is a combination of 3 drugs in 2 pills to treat HIV. The 3 drugs are dolutegravir, emtricitabine and tenofovir disoproxil fumarate. **Neither B/F/TAF nor DTG + F/TDF are approved for the treatment of HBV.**

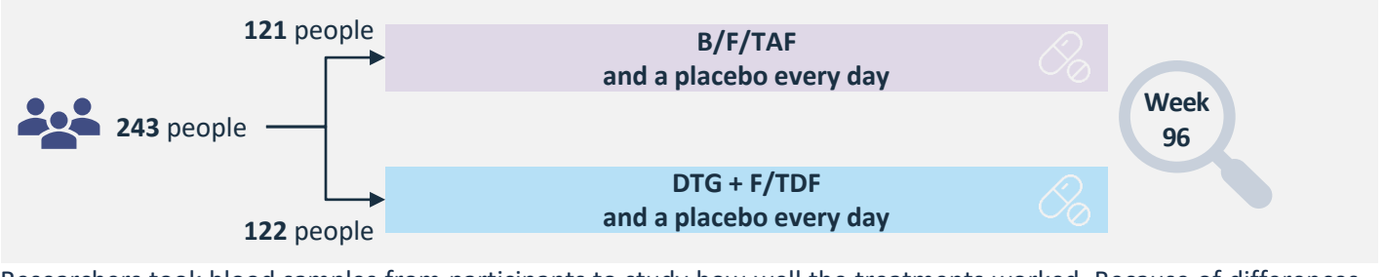
The study compared B/F/TAF and DTG + F/TDF as first treatments for HIV and HBV in people with both viruses. The people included in the study had not taken any medicine for HIV or HBV before starting these treatments. The study collected information about how the treatments affected the health of people with both HIV and HBV. **Here is a summary of some of the main findings of the study.**

Why did researchers do this study?

Researchers wanted to learn how well B/F/TAF works and how safe it is as a first treatment in adults with both HIV and HBV, compared with DTG + F/TDF. At the halfway point of the study, vast majority of people had suppressed HIV with both treatments, and B/F/TAF was slightly better than DTG + F/TDF at lowering HBV levels. **The results at the study's halfway point (48 weeks) have been summarized previously** (Avihingsanon A, et al. AIDS 2022; Oral presentation OALBX0105).

Who took part in the study and how was the treatment studied?

A total of 243 people with both HIV and HBV took part in the study. The participants were randomly divided into 2 groups, with about half taking B/F/TAF and the other half taking DTG + F/TDF. The treatments were given for 96 weeks. Everyone in the study also received a placebo (a tablet without active medication) to mask who was getting which active medicine. **This summary looks at how well the treatments worked and how safe they were after 96 weeks (almost 2 years)**.



Researchers took blood samples from participants to study how well the treatments worked. Because of differences between the 2 viruses, they used different ways to test how well the treatments were working for HIV and HBV.

HIV

If an HIV treatment works, the amount of virus in a person's blood drops to levels that are too low to be seen on regular laboratory tests (that is, "undetectable"). In this study, a level of less than 50 copies of the virus in 1 milliliter of blood was considered undetectable. This is also called viral suppression.

HBV

For HBV, the levels of virus in the blood are measured in international units per milliliter of blood (shortened to IU/mL). In this study, a level of less than 29 IU/mL was considered a sign that the treatments were working well. Researchers used blood tests to measure 2 HBV antigens (proteins found in the body of people with HBV) called HBeAg and HBsAg, and their associated antibodies (immune system proteins produced in response to specific antigens). Loss of HBeAg or conversion to the antibody (seroconversion) means that the HBV has become inactive. Loss of HBsAg or seroconversion means that HBV should remain suppressed even if the treatment is stopped (functional cure). Researchers also tested how well the liver was working.

They also looked at the side effects (unwanted effects of the treatment) to see which ones might have been caused by B/F/TAF or DTG + F/TDF.

Talk to your healthcare provider if you have questions about this topic or about HIV and/or HBV treatment.

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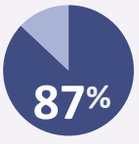
What were the results of the study?

How well did the two treatments work in people with both HIV and HBV?

HIV suppression (virus level less than 50 copies/mL)

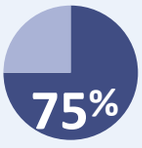


of people taking **B/F/TAF** had HIV level less than 50 copies/mL

of people taking **DTG + F/TDF** had HIV level less than 50 copies/mL

Most people who took B/F/TAF or DTG + F/TDF had HIV suppression after 96 weeks of therapy. The results were similar between the two treatments.

HBV suppression (virus level less than 29 IU/mL)



of people taking **B/F/TAF** had HBV levels less than 29 IU/mL

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Most people who took B/F/TAF or DTG + F/TDF had HBV suppression after 96 weeks of therapy. The results were similar between the two treatments.

Results of other HBV-related tests

More people receiving B/F/TAF had HBeAg loss or seroconversion at 96 weeks compared with people taking DTG + F/TDF, indicating that the virus was inactive in more people after B/F/TAF treatment. Rates of HBsAg loss or seroconversion and normalization of liver function were similar in both groups after 96 weeks, with a tendency toward better results in people receiving B/F/TAF.

How many people had side effects or unwanted medical events from the study treatments?

Side effects of study treatments were similar for both groups.

For every 100 people taking B/F/TAF:	For every 100 people taking DTG + F/TDF:
29 people had side effects thought to be related to **B/F/TAF**. Of these:	**28 people** had side effects thought to be related to **DTG + F/TDF**. Of these:
8 people had **weight gain**	**10** people had **weight gain**
2 people had an **increase in the liver enzyme alanine aminotransferase (ALT)**	**7** people had an **increase in the liver enzyme alanine aminotransferase (ALT)**

Less than 1 in 100 people stopped taking the study treatment because of unwanted medical event

Out of the 243 people, only 1 person stopped taking B/F/TAF early due to an unwanted medical event. This unwanted medical event (liver cancer) was not related to B/F/TAF treatment.

One person in the B/F/TAF group had a serious side effect (fungal infection, which later resolved on treatment). There were 3 people who died during the 96-week period: 2 in the B/F/TAF (1 due to heart disease and 1 due to unknown cause) and 1 in the DTG + F/TDF group (due to unknown cause). Researchers found that their deaths were not related to the study treatments.

Please scan or click the QR code to either:

- **View or download a copy of this summary online**
- **View or download the original scientific presentation on which this summary is based**
- **View link to the simultaneous publication at Lancet HIV**

Reference: Avihingsanon A, et al. IAS 2023; E-poster

Poster Conclusions

In people with both HIV and HBV who had not received treatment before, who then took B/F/TAF or DTG + F/TDF for 96 weeks, the study showed that:

- Rates of HIV and HBV suppression were high for both treatments
- B/F/TAF showed higher rates of HBeAg loss and seroconversion than DTG + F/TDF through 96 weeks
- Rates of HBsAg loss or seroconversion were high (meet criteria for functional cure) in both groups but slightly higher in people receiving B/F/TAF
- The number of side effects was similar between treatment groups

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