

The BICSTaR study of B/F/TAF for HIV treatment: A summary of results in people who have previously taken other HIV medicines and had HIV resistance mutations

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This is a plain language summary of a scientific poster that was originally presented by Dr Trottier at IDWeek 2023 (Poster 1528848). This plain language summary only presents selected data and is not intended to replace the full poster. Please refer to the poster (available by QR code at the end of this document) for full details.

Background

HIV medicines reduce the amount of virus in a person's blood (viral load). When the HIV levels do not drop after starting a medicine (or drop and go back up), it may mean that the virus has genetic changes (mutations), and these mutations might stop a medicine from working properly. We call these resistance mutations.

B/F/TAF is a single pill to treat HIV that combines three medicines: bictegravir (B), emtricitabine (F) and tenofovir alafenamide (TAF). B/F/TAF is for people who have not taken HIV medicines before or for people who are replacing their current HIV medicines.

The BICSTaR study provides new information about using B/F/TAF in day-to-day life, which may be different from a clinical trial. **This BICSTaR summary is about people living with HIV that is resistant to certain medicines and who have taken other HIV medicines before switching to B/F/TAF.**

Why are researchers doing this study?

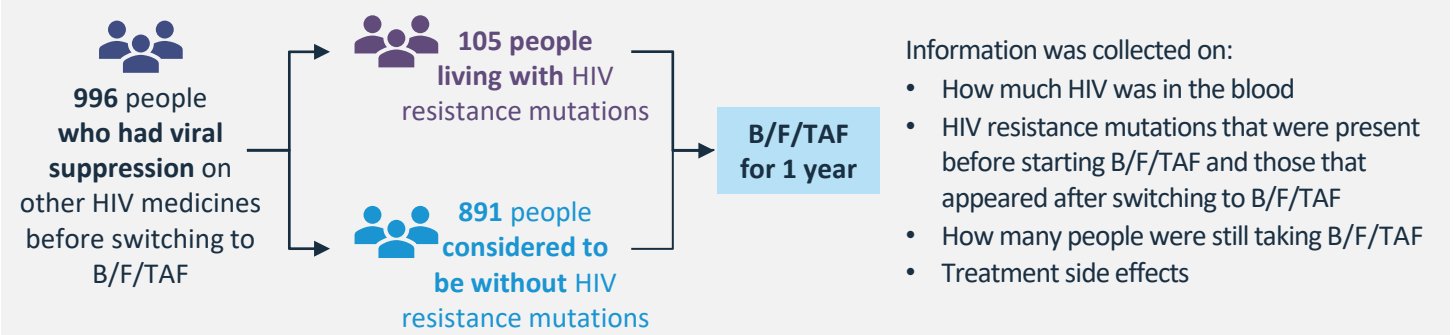
The BICSTaR study is providing information on the use of B/F/TAF for the treatment of HIV in day-to-day life. In this analysis, researchers wanted to learn how well B/F/TAF works and how safe it is in adults with and without HIV resistance mutations.



Viral load and viral suppression: If an HIV treatment works, the amount of virus in a person's blood (viral load) drops to levels that are too low to be detected in routine lab tests (that is, "undetectable"). This is also called viral suppression. In this study, viral suppression occurred when less than 50 copies of the virus were found in 1 milliliter of blood.

Who is taking part in the study and how is the treatment studied?

This summary looks at the 1-year results of 996 adults from different countries around the world who had achieved viral suppression with other HIV medicines before they switched to B/F/TAF during this study.



What are the results of the study?

Who had HIV resistance mutations?

Researchers observed that on average*, people with HIV resistance mutations were more likely to



be aged 50 years and older



have taken more medicines before switching to B/F/TAF



have a longer time between HIV diagnosis and switching to B/F/TAF



have a history of not having achieved or maintained viral suppression

*Based on numerical values only, no statistical testing was performed

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What are the results of the study?

How well did B/F/TAF work in people taking it for 1 year?

Researchers looked at how well B/F/TAF worked (virologic suppression) by measuring HIV levels in the blood. This was calculated in 2 different ways.

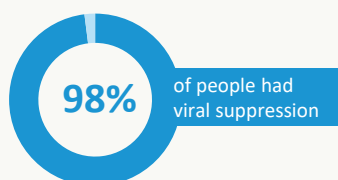
Missing = excluded analysis

Some people had missing information. This means that they stopped taking B/F/TAF before the 1 year was over or they did not have information on levels of HIV in their blood. So, these people were **not included in the analysis**.

People **with HIV** resistance mutations before taking B/F/TAF:



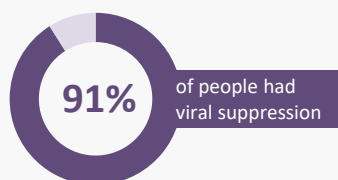
People **without HIV** resistance mutations before taking B/F/TAF:



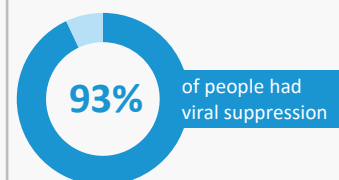
Discontinuation = failure analysis

Some people stopped taking B/F/TAF (discontinued) before the 1 year was over, for any reason, were counted as having not achieved viral suppression. Missing data for other reasons were excluded.

People **with HIV** resistance mutations before taking B/F/TAF:



People **without HIV** resistance mutations before taking B/F/TAF:



How many people continued taking B/F/TAF for 1 year?

88% of people were still taking B/F/TAF at 1 year.

How many people developed new HIV resistance mutations after switching to B/F/TAF?

There were zero new resistance mutations reported in people with HIV switching to B/F/TAF.

How many people taking B/F/TAF had side effects?

For every 100 people taking B/F/TAF:

- **13 people** had a side effect during the study that was considered to be related to B/F/TAF
- **6 people** stopped taking B/F/TAF due to side effects (related to B/F/TAF) (the most common reasons were weight gain, headache and feeling tired)

Only 2 out of 996 people overall had serious side effects related to B/F/TAF (both were related to depression).



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- View or download a copy of this summary online
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Poster Conclusions

After 1 year of people taking B/F/TAF in everyday life, researchers found:

- Most people had viral suppression despite having HIV resistance mutations before switching to B/F/TAF
- B/F/TAF did not lead to development of new HIV resistance mutations
- Most people were still taking B/F/TAF at 1 year
- Most people did not have side effects related to B/F/TAF

Reference: Trottier B, et al. IDWeek 2023, Poster 1528848