Caution needed when interpreting the results of simplification studies

There is much excitement from researchers about finding new ways to use dolutegravir (Tivicay and in Triumeq). In this issue of TreatmentUpdate we present some results from small and generally short simplification trials with dolutegravir (and other drugs). However, because of their design, these studies raise many issues, which have yet to be addressed. Here are some examples:

- What is the long-term effectiveness of dolutegravir monotherapy?
- In people who use potent combination anti-HIV therapy (ART), HIV continues to infect cells and replicate at low levels in lymph nodes and lymphatic tissue. Some researchers think that this continued replication in lymphatic tissues is one of the reasons ART is unable to cure HIV. What happens in these locations with simplified therapy?
- HIV affects the brain. Is simplified therapy with dolutegravir sufficient to maintain a person’s neurocognitive abilities?
- HIV-positive people who use ART and maintain an undetectable viral load in the blood and who do not have sexually transmitted infections are highly unlikely to sexually spread HIV. Is simplified therapy with dolutegravir able to suppress levels of HIV in the genital tract?
- Is simplified therapy with two drugs, such as dolutegravir + 3TC, equivalent in potency to therapy with dolutegravir + two other drugs?
- Does the reservoir, or burden, of HIV-infected cells increase, decrease or stay the same with simplification therapy?
- HIV is associated with inflammation and activation of the immune system, even in people who take ART. This inflammation/activation may increase the risk for complications over the long term. What effect does simplification therapy have on inflammation/activation of the immune system?

Until robustly designed clinical trials can provide clear answers to these and other related questions, we urge our readers to be cautious about interpreting the preliminary results from simplification therapy that they may hear or read about. Furthermore, treatment guidelines in Canada and the U.S. do not recommend the use of such simplified therapy with dolutegravir.

—Sean R. Hosein

REFERENCES:

Disclaimer

Decisions about particular medical treatments should always be made in consultation with a qualified medical practitioner knowledgeable about HIV- and hepatitis C-related illness and the treatments in question.

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