Injection-Site Reactions Associated with the Use of Long-Acting Cabotegravir for Pre-Exposure Prophylaxis

Summary

- Injection-site reactions (ISRs) were frequently reported during the Injection Phases of the HPTN 083 and HPTN 084 clinical trials.
- **HPTN 083**
  - Among participants who received at least 1 injection:
    - Drug-related ISRs were reported in 81.4% of participants in the long-acting cabotegravir (CAB LA) group compared to 31.3% of participants in the tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) group. Injection site pain was the most frequently reported ISR.
    - In CAB LA participants who reported an ISR, most were Grade 1 (34%) or Grade 2 (46%). There were no Grade 4 or 5 ISRs.
    - ISRs leading to discontinuation from study occurred in 2.4% of participants in the CAB LA group. No one in the TDF/FTC group discontinued from the study due to ISRs.
- **HPTN 084**
  - At least one drug-related ISR was reported in 32% of participants in the CAB LA group compared to 9% in the TDF/FTC group.
  - No subjects discontinued study drug due to an ISR in either treatment group.
- Important Safety Information and Boxed Warning can be found in the Prescribing Information and can also be accessed from the Our HIV Medicines section of viivhealthcare.com/us.

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HPTN 083

HPTN 083 is a randomized, double-blind, phase 2b/3, non-inferiority study designed to assess the safety and efficacy of CAB LA compared to daily oral TDF/FTC for pre-exposure prophylaxis (PrEP) in HIV-uninfected cisgender men and transgender women who have sex with men.[1]

ISRs were reported in 81.4% (1724/2117) of participants who received at least one injection of CAB LA, compared to 31.3% (652/2081) in the TDF/FTC group.[1] The maximum severity of ISRs reported was mild (Grade 1, 34% of participants), moderate (Grade 2, 46% of participants), or severe (Grade 3, 3% of participants). No participant experienced a Grade 4 ISR.

Of the 10,666 ISRs in the CAB LA group, 6486 (61%) were pain and 2530 (24%) were tenderness.[1] The proportion of participants reporting ISRs at each visit and the severity of the ISRs decreased over time. Events began at a median (IQR) of 1 day (0-2) with a median (IQR) duration of 3 days (2-6). ISRs leading to discontinuation from the study occurred in 2.4% (50/2117) of participants in the CAB LA group. See Figures 1 and 2.

Figure 1. Injection Site Reactions Over Time[1]

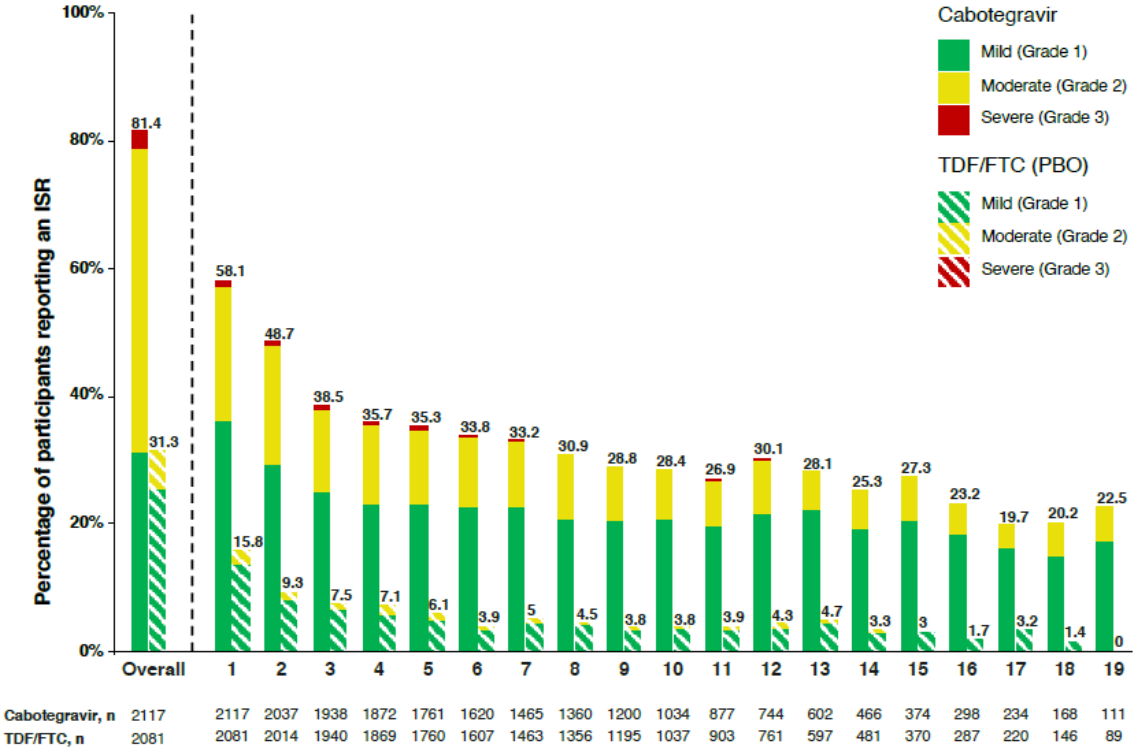
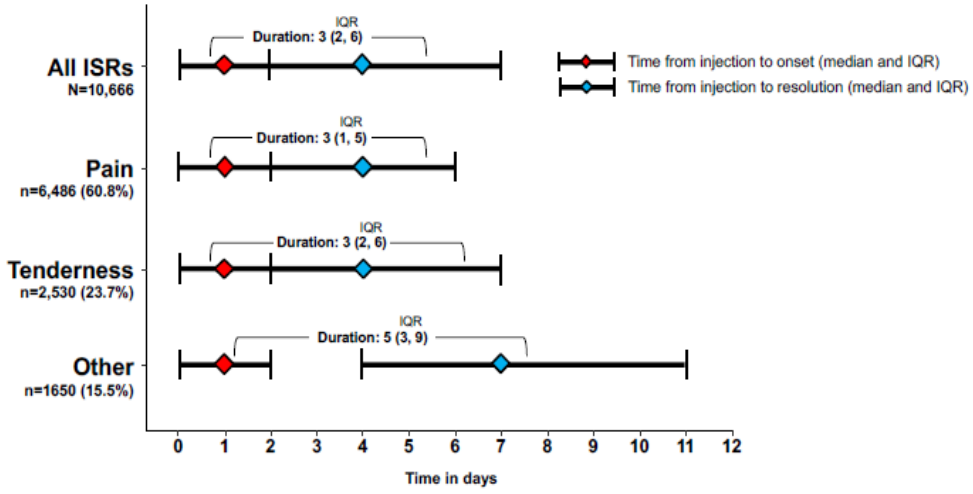


Figure 2. Injection Site Reactions: Timing and Duration[1]



HPTN 084

HPTN 084 is a double-blind, placebo-controlled, phase 3, superiority trial evaluating the safety and efficacy of long-acting injectable cabotegravir compared to daily oral TDF/FTC for pre-exposure prophylaxis in HIV-uninfected cisgender women.[2] The study design of HPTN 084 was similar to HPTN 083.

ISRs were reported in 32% of participants who received CAB LA versus 9% of participants who received TDF/FTC plus CAB LA placebo.[2] Most ISRs occurred in the CAB LA arm after the injections at Week 1 and the incidence decreased over time. Grades 1 or 2 ISRs were reported in 7% of participants who received CAB LA versus 1% who received TDF/FTC. There were no discontinuations due to ISRs in either arm.

MANAGEMENT OF INJECTION-SITE REACTIONS

No specific treatments for ISRs were evaluated in HPTN 083 or HPTN 084. Medical judgement should be used to determine how best to manage ISRs associated with CAB LA (e.g., oral analgesics, application of a hot or cold pack, etc.).

This information is scientific and non-promotional in nature and is not intended for further distribution.

This information is not intended to offer recommendations for using this product in a manner inconsistent with its approved labeling. Please consult the Prescribing Information. For ViiV Healthcare to monitor the safety of our products, we encourage healthcare professionals to report adverse events or suspected overdoses to the company at 877-844-8872.

Selection of references follows principles of evidence-based medicine and, therefore, references may not be all inclusive.

REFERENCES

1. Landovitz R DD, Clement ME, et al. Cabotegravir for HIV prevention in cisgender men and transgender women. *NEJM*. 2021;385(7):595-609. . doi:http://dx.doi.org/10.1056/NEJMoa2101016.
2. Delany-Moretlwe S. Long acting injectable cabotegravir is safe and effective in preventing HIV infection in cisgender women: results from HPTN 084. Presented at HIV Research for Prevention Conference (HIVR4P), January 27-28 and February 3-4, 2021 (Virtual).