

## **ABSTRACT**

Side effects of antiretroviral drug use by HIV-positive patients have been extensively studied; however, there are limited data on the side effects of antiretroviral drugs used as an HIV prophylaxis among healthy, HIV-negative individuals. Here we report on an unusual neuropathy in a 24-year-old participant in the FEM-PrEP trial. This was a Phase III randomized, double blind, placebo-controlled trial to test the safety and effectiveness of tenofovir disoproxil fumarate (300 mg) and emtricitabine (200 mg) (TDF-FTC) to prevent HIV. At the eighth week of taking TDF-FTC with moderate adherence, the participant complained of mild paresthesiae, numbness, and a tingling sensation in her upper limbs that was associated with pain and cold. After an additional 4 days, she developed a disabling weakness of her upper limbs and tremors in her hands. The study product was discontinued, and within 2 weeks she was free of all symptoms. One month after restarting the drug, she complained of posture-dependent numbness of her upper limbs. Results of clinical and neurological exams, laboratory tests, and magnetic resonance imaging are described here.