Case Study: Expedited Reporting via DAERS

The participant is a 38 year old, HIV infected, Black female, who enrolled in the A5288 study in the Republic of South Africa on May 19, 2016.

On May 18, 2016, during the screening visit, the participant's CD4 count was 143 cells/mm^3 and her HIV viral load was 80,112 copies/mL. Her pregnancy test was negative. All other laboratory tests and the physical examination were normal.

On May 19, 2016, the participant was enrolled in the study onto cohort B3. On the same day, the participant started receiving the study products, emtricitabine/tenofovir disoproxil fumarate, 200/300 mg oral (PO) daily (QD), raltegravir 400 mg PO twice daily (BID), darunavir 600 mg PO BID and ritonavir 100 mg PO BID.

On June 15, 2016, at the week four study visit, the participant had no complaints and the physical examination was normal.

On June 24, 2016, the participant went to the study clinic with complaints of abdominal pain, diarrhea, vomiting, and nausea, all of which had started on June 22, 2016. The participant was found to be moderately dehydrated. She reported taking her study products as prescribed the night of June 23, 2016, but did not take anything before arriving at the clinic. The study physician assessed the symptoms as grade 3. The study physician suspected gastroenteritis and referred the participant to the hospital for further management. Upon admission to the hospital, she was given IV fluids for rehydration and ondansetron (Zofran) for nausea. Blood was taken for a complete blood count and serum electrolytes. The study products were continued without change.

Later on June 24, 2016, an abdominal ultrasound was performed and the results were normal. Her complete blood count showed a white blood cell count of 11.18 $x10^3$ /µL (normal range: 4.00-10.00), and the rest of the parameters were within normal ranges. Her serum electrolytes revealed a sodium of 129 mmol/L (normal range: 136-145), potassium of 3.1 mmol/L (normal range: 3.3-5.3), and chloride of 94 mmol/L (normal range: 99-113). A stool sample was collected and the results are pending. The participant started to improve on the treatment.

On June 27, 2016, the participant's condition improved and she was discharged with a diagnosis of presumed gastroenteritis that was assessed as grade 3. At discharge, she had residual abdominal pain for which she was prescribed paracetamol 500 mg orally as needed.

The site Principal Investigator has assessed the event of presumed gastroenteritis as not related to the study products, emtricitabine/tenofovir disoproxil fumarate, raltegravir, darunavir and ritonavir.

Past medical/surgical history: The participant is HIV infected with no significant past medical history. No history of trauma or illness.

Ob/Gyn history: Gravida 2, Para 2. Currently on Depo-Provera (medroxyprogesterone acetate) injections for contraception.

Social history: The participant occasionally consumes alcohol.

Concomitant medications: Depo-Provera (medroxyprogesterone acetate) injections for contraception since April 2013. Ibuprofen as needed for pain for the past ten years. Multivitamin as a daily supplement for the past ten years.

UPDATE

On July 18, 2016, the study physician evaluated the participant in the clinic during a follow-up visit. The participant reported that the abdominal pain had resolved. She had no complaints and the physical examination was normal. The participant provided a copy of the discharge summary.