Case Study: Expedited Reporting via DAERS

The participant is a 25 year-old, HIV uninfected, African American female, who enrolled in the HVTN 076 study in the United States on November 18, 2015.

On November 6, 2015, during the screening visit, the participant's HIV test and pregnancy test were negative. All other laboratory tests and the physical examination were normal.

On November 18, 2015, the participant was enrolled in the study. On the same day, the participant received the first administration of the study product, VRC-HIVDNA016-00-VP, 1 mL, intramuscularly (IM) in the left deltoid.

On December 16, 2015, at the month one study visit, the participant received the second administration of the study product, VRC-HIVDNA016-00-VP, 1 mL, IM in the left deltoid.

On January 14, 2016, at the month two study visit, the participant received the third administration of the study product, VRC-HIVDNA016-00-VP, 1 mL, IM in the left deltoid.

On May 18, 2016, at the month six study visit, the participant received the first administration of the study product, VRC-HIVADV014-00-VP, 1 mL, IM in the left deltoid.

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. 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. Prior to the onset of the AE, the participant completed the course of treatment with the study products VRC-HIVDNA016-00-VP and VRC-HIVADV014-00-VP.

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 assessed the event of presumed gastroenteritis as not related to the study products, VRC-HIVDNA016-00-VP and VRC-HIVADV014-00-VP.

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

Ob/Gyn history: Gravida 0, Para 0. No history of sexually transmitted infections, pelvic inflammatory disease, or urinary tract infections. 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.