

Case Study: Expedited Reporting via DAERS

The subject is a 25 year old, HIV-uninfected, Black male, who enrolled in the HVTN 100 study in the Republic of South Africa on May 18, 2015.

On April 31, 2015, during the screening visit, the subject reported pre-existing asymptomatic proteinuria. All other laboratory tests and the physical exam were normal.

The subject's last HIV status test date was May 7, 2015, and the result showed the subject was uninfected.

On May 18, 2015, the subject was enrolled in the study and assigned to Group 1. On the same day, the subject received the first administration of the study vaccine, ALVAC-HIV (vCP2438) OR Placebo for ALVAC-HIV (vCP2438), 1mL intramuscularly (IM) in the left deltoid.

On June 15, 2015, the subject received the second administration of the study vaccine, ALVAC-HIV (vCP2438) OR Placebo for ALVAC-HIV (vCP2438), 1mL IM in the left deltoid.

On June 22, 2015, the subject went to the emergency department with complaints of diarrhea, vomiting, abdominal pain, and nausea, which had all started on June 20, 2015. The attending physician assessed all of these symptoms as grade 3. Upon admission to the hospital, he was given IV fluids for rehydration and ondansetron (Zofran) for nausea. Blood was taken for a complete blood count and serum electrolytes.

Later on June 22, 2015, an abdominal ultrasound was performed and the results were normal. His complete blood count showed a white blood cell count of $11.18 \times 10^9/L$ (normal range: 4.00-10.00), the rest of the parameters were within normal ranges. His 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 subject started to improve on the treatment.

On June 24, 2015, the subject was discharged with a diagnosis of presumed gastroenteritis that was assessed as a grade 3. At discharge, he had residual abdominal pain.

On June 25, 2015, the subject informed the study site about his visit to the hospital. At the time of reporting the event to the study site, the subject stated that he was doing better but still had residual abdominal pain. The study vaccine regimen will be continued without change.

The site Principal Investigator has assessed the event of presumed gastroenteritis as not related to the study vaccine, ALVAC-HIV (vCP2438) OR Placebo for ALVAC-HIV (vCP2438).

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

Social history: The subject smokes one pack of cigarettes a day and does consume alcohol.

Concomitant medications: Ibuprofen (used for pain as needed for the last ten years).
Multivitamin (used as a supplement for the last ten years).

UPDATE

On June 30, 2015, the study physician evaluated the subject in the clinic. The subject reported that the abdominal pain had resolved. Physical examination had no abnormal findings. The subject provided a copy of the discharge summary.