

Case Study: Expedited Reporting via DAERS

The subject is a 25 year old, HIV uninfected, Black female, who enrolled in the MTN-020/ASPIRE study in the Republic of South Africa on May 18, 2015.

On April 31, 2015, during the screening visit, the subject's HIV test and pregnancy test were negative. All other laboratory tests and the physical examination were normal.

On May 18, 2015, the subject was enrolled in the study. On the same day, the subject started receiving the study product, Dapivirine Vaginal Ring OR Placebo for Dapivirine Vaginal Ring, 25 mg, vaginal, once a month.

On June 18, 2015, at the month one study visit, the subject had no complaints and the physical examination was normal.

On June 26, 2015, the subject went to the study clinic with complaints of abdominal pain, diarrhea, vomiting, and nausea, all of which had started on June 24, 2015. The study physician assessed the symptoms as grade 3 and the study product was continued without change. The study physician suspected gastroenteritis and referred the subject 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.

Later on June 26, 2015, an abdominal ultrasound was performed and the results were normal. Her complete blood count showed a white blood cell count of $11.18 \times 10^9/L$ (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 subject started to improve on the treatment.

On June 28, 2015, the subject'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 product, Dapivirine Vaginal Ring OR Placebo for Dapivirine Vaginal Ring.

Past medical/surgical history: The subject is HIV uninfected with no significant past medical history. No 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 subject 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 17, 2015, the study physician evaluated the subject in the clinic at the month two study visit. The subject reported that the abdominal pain had resolved. She had no complaints and the physical examination was normal. The subject provided a copy of the discharge summary.