

## Case Study: Acute Chest Pain

The subject was a 36 year old, HIV infected, female, enrolled in the study in Uganda on 6 Feb 2014, who died on 20 Mar 2014 and the cause of death was acute chest pain.

At the screening visit, the subject reported a week long history of shortness of breath. The chest examination was positive for bilateral wheezes. The subject was noted to be in mild respiratory distress with mild pallor. Chest X-ray was normal. The subject was prescribed oral antibiotics.

On 6 Feb 2014, the subject was enrolled in the study and randomized to Arm 1C of the study. At study entry, the subject was stable without any respiratory distress. Her baseline HIV viral load was 20,241 copies/mL and absolute CD4 cell count 49 cells/mm<sup>3</sup>.

On 7 Feb 2014, the subject was started on the study agents paclitaxel 176 milligrams (mg) intravenous every three weeks and efavirenz/emtricitabine/tenofovir disoproxil fumarate 200/300/600 mg oral every day.

At the week 3 study visit, the subject complained of mild cough, shortness of breath, mild diarrhea, and vomiting for the previous three days. She appeared ill with mild respiratory distress. Chest examination showed wheezes on the anterior left side of the chest. An impression of pneumonia was made and the subject was initiated on intravenous ceftriaxone and oral amoxicillin clavulanate. Chest X-ray showed no radiological abnormalities. The subject was sent home on plenty of fluids after chemotherapy.

On 13 Mar 2014, the subject reported to the study clinic complaining of moderate epigastric pain not associated with food. She had occasional mild diarrhea without blood. Physical examination showed a stable subject with mild pallor but not in respiratory distress or dehydrated. Chest examination was clinically clear. Moderate epigastric tenderness was noted but no masses were felt. The subject was treated for moderate gastritis with omeprazole, Relcer gel and Co-codamol (paracetamol/codeine phosphate).

On 20 Mar 2014, the subject's husband informed the study site that the subject complained of acute chest pain around midnight and died at 0300 hours before being able to reach the hospital. No postmortem was performed. A copy of the death certificate is not available.

The site Principal Investigator has assessed the event of death due to acute chest pain as not related to the study agents paclitaxel and efavirenz/emtricitabine disoproxil fumarate.

Past Medical History: HIV infection.

Obstetric and Gynecological History: None provided.

Social History: None provided.

*This case study was developed from an actual EAE submission. All subject identifiers have been removed to maintain confidentiality.*

## **UPDATE**

On 26 Mar, 2014, the subject's husband visited the study clinic and provided a copy of the death certificate.