

Study Category

Defining Nevirapine Toxicity

Title

A Case-control Toxicogenomics Study to identify Unique Genetic Polymorphisms in Patients who have experienced symptomatic Hepatotoxicity or Severe Cutaneous Toxicity within the first 8 weeks of Nevirapine Therapy

Principal Investigator at TGH

Dr. Sharon Walmsley

Sponsor

Boehringer Ingelheim

Brief Description of Study

This is a case controlled study to identify if there are any unique genetic polymorphisms that may identify patients at risk for developing symptomatic hepatotoxicity or severe cutaneous toxicity observed during the first 8 weeks of nevirapine therapy . this may enable us to prevent putting patients at risk of these toxicities if we can screen them prior to initiating therapy.

Case Subject:

- Male or female >18 years of age with HIV-1 Infection who experienced one or more of the following adverse reactions within the first 8 weeks of starting nevirapine therapy:
- Grade 3 or 4 liver function test elevation with any symptom consistent with clinical hepatitis
- Acute liver failure secondary to Nevirapine therapy
- Functional grade III or IV nevirapine related cutaneous toxicity.

Control Subject:

Male or female > 18 years of age with HIV-1 Infection who have been exposed to nevirapine therapy for at least 8 weeks and who did not meet the “case” definition

Contact Person

Currently enrolling

Anna Buss at (416) 340-4239, e-mail anna.buss@uhn.on.ca