

PHACS SMARTT Protocol Participant Summary

Title: A Trigger-Based Design for Evaluating the Safety of *in utero* Antiretroviral Exposure in Uninfected Children Born to HIV-infected Mothers

Authors: Paige L. Williams, Russell Van Dyke, George R Seage, Ray Griner, Denise Jacobson, Susan Brogly, Katherine Tassiopoulos, Yanling Huo, Rohan Hazra, George Siberry, Jennifer Read, Lynne Mofenson and Kenneth Rich for the PHACS Team.

Study Description: Treating women who are HIV infected with antiretroviral drugs has helped lower the number of babies born with HIV infection. However, we still need to see if HIV medicines taken by pregnant women cause problems in their children as they grow up. We designed a large study in the United States to look at how safe these HIV medicines are for the babies born to mothers with HIV infection. The study is called SMARTT, which stands for **Surveillance Monitoring for Antiretroviral Therapy Toxicities**. The children are seen once each year. We first look at some measures that are easy to collect. This helps make the visits shorter and less expensive. We do blood tests and collect height and weight measurements. We also test for learning, hearing or language problems. If any of these tests are not normal, we call this “meeting a trigger”. If a child meets a trigger, we do other follow-up tests to learn more about the problems.

Study Population: The SMARTT study started in March 2007. As of January 2009, 1459 babies and children had enrolled in the study, and 1284 had their first study visit. The children were all born to mothers with HIV infection. They were aged 0 to 12 years at enrollment.

Results: Of the 1284 babies and children who had a study visit, 354 (28%) met at least one trigger. Over half of the 354 children who met a trigger had a high body mass index (BMI). This means they weighed a lot given how tall they were. One third of the 354 who met a trigger had problems with language or hearing. The children who met the BMI trigger had blood tests done to see if there were more serious problems with their metabolism, or the way their bodies use energy. Of the children with blood tests, one fourth had high cholesterol or other metabolic problems. We want to know what percent of all of the children in SMARTT have metabolic problems. Based on past studies, we assumed that 90% with metabolic problems also have high BMI. We then estimate that 6.4% of all SMARTT children had these types of metabolic problems. This estimate is more precise than if we had just picked the same number of children at random to look for metabolic problems.

Conclusions: The trigger design of the SMARTT study helps keep the study visits shorter and makes the study less expensive. It also makes it easier to find children who might have serious problems. We found that problems with metabolism and with language or hearing were common among young children born to mothers with HIV infection. Almost all (98%) of the children have stayed on the study so far. It is important to keep studying these children as they grow up.

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